AGRICULTURAL BIOTECHNOLOGY AND TRANSATLANTIC TRADE: AN INTERNATIONAL POLITICAL ECONOMY ANALYSIS OF SOCIAL REGULATORY BARRIERS

Ph.D. Dissertation

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ABSTRACT

The development and commercialisation of genetically modified (GM) agricultural crops has drawn attention to a complex challenge facing trade diplomacy – the challenge of regulatory regionalism created by *social regulatory barriers*. *Social* regulations associated with GM crops have been enacted to ensure food safety, environmental protection and moral, ethical and religious preferences. Regulatory regionalism exists at the transatlantic level where GM crops approved as safe in North America have been delayed or denied market access in the EU because of divergent social regulations.

As domestic social regulations have emerged on the trade agenda trade diplomacy is at a crucial crossroads because the traditional integration approach of trade diplomacy fails to acknowledge the endogenous political economy factors responsible for the social regulations within a particular jurisdiction. The research reveals that maintaining the traditional approach will erode public support for trade diplomacy and marginalise it as a viable force in international integration.

Given the shortcomings of the traditional trade approach, this study then identifies a regulatory development and integration framework contributing to regulatory stability and enhancing the potential for transatlantic regulatory integration. This Ideal Regulatory Framework essentially builds social credence into the scientific rationality approach. Social credence is built in by ensuring consumer information, trust and choice. The result is a trade diplomacy approach that contributes to regulatory stability and integration by balancing the competing interests within an operational, dynamic, rules-based approach capable of managing the social concerns associated with advanced technologies such as GM crops.

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PART I THE ISSUES

The international trade of genetically modified (GM) agricultural crops has drawn attention to a controversial and complex challenge facing trade diplomacy – the challenge of regulatory regionalism created by *social regulatory barriers* to trade. In fact, the thesis of this study is that this challenge leaves trade diplomacy at a crucial crossroads. Applying the traditional approach of trade liberalisation to the market access barriers caused by regulatory regionalism will increasingly erode public support for the international trade regime and marginalize trade diplomacy as a viable force in international integration. Amending the traditional trade liberalisation approach will instead enhance the prospects that trade diplomacy can effectively deal with regulatory regionalism and promote international integration. Essentially, the objective of this study is to define the traditional trade diplomacy approach, identify why it is unable to address the challenge of regulatory regionalism associated with GM crops and, given the shortcomings, how that approach may be amended to effectively address this challenge.

Perhaps the most intriguing aspect of the fact that trade diplomacy now faces this crucial crossroads is that trade diplomacy has arrived here because of its success. The objective of trade diplomacy is to enhance market access for traded products (including goods, services and investments) by removing barriers to trade. Initially, trade diplomacy was focused on reducing or removing border measures such as tariffs and quantitative restrictions by establishing rules that disciplined the type of border measures that trading partners could apply against foreign products. As border measures have come under international discipline, domestic regulations have assumed a greater importance as a source of trade barriers. Domestic regulations may become the basis for trade barriers against foreign products whose production, processing or composition contravenes domestic preferences embodied in the regulations. When regulatory approaches differ between jurisdictions regulatory regionalism is created potentially hindering market access and generating trade tensions. Given the success of trade diplomacy in disciplining border measures, the same approach has been used to discipline the type of regulations that governments can introduce. Hence, trade diplomacy now faces the challenge of regulatory regionalism because its success in dealing with traditional border measures has allowed domestic regulations to emerge on the trade agenda.

Yet, as trade diplomacy disciplines the type of domestic regulations that nation-states may use it reaches deep into areas of national competence and enters controversial territory. Indeed, the 1999 Ministerial Meeting of the World Trade Organization (WTO) in Seattle, besieged by a vast coalition of interest groups, exemplified the controversy that arises when traditional trade diplomacy and domestic regulations interact. In fact, the development, commercialisation and international trade of GM crops has been portrayed as the epitome of an invasive trade diplomacy strategy designed to strip nation-states of their regulatory policy autonomy in order to serve the profit-maximisation interests of faceless multinational corporations. Given such a sensational and negative view of trade diplomacy it is not difficult to understand why regulatory regionalism and regulatory barriers represent a controversial and complex challenge to trade liberalisation efforts. But from where has this view of trade diplomacy emerged? And, perhaps more importantly, is this view accurate?

Clearly, as domestic regulations increasingly emerge on the trade agenda, the time has come for a critical assessment of the problems associated with applying the traditional trade diplomacy approach to the market access problems of regulatory regionalism and regulatory trade barriers. Moreover, it appears that there is no better case study of this trade diplomacy challenge than the international trade of GM crops. The development and commercialisation of GM crops has prompted the establishment of what may be called *social* regulations to ensure domestically preferred levels of food safety, environmental protection and to address broader social norms such as moral, ethical and religious concerns about the use of advanced technologies. These *social* regulations are fundamentally shaped by endogenous political economy factors that can be quite unique to a particular regulatory jurisdiction. In fact, differing political economy factors within North America and the European Union have produced transatlantic regulatory regionalism where GM crops approved as safe in North America and widely used in commercial production have been delayed and denied market access in the European Union because of *social regulatory barriers*. While Canada and the United States have proposed dealing with the trade tensions through the traditional trade diplomacy approach of the WTO, the European Union has rejected this course of action. In other words, a transatlantic stalemate has emerged with no apparent method in sight for dealing with the regulatory regionalism.

Therefore, this study is a critical assessment of the traditional trade diplomacy approach in the context of the transatlantic regulatory regionalism associated with GM crops. This critical assessment is built on the fundamental proposition that overcoming regulatory regionalism requires a strategy of regulatory integration, yet the prospects and limits of regulatory integration are a function of the domestic regulatory development process shaped by endogenous political economy factors. Hence, in order to identify the degree of concert or conflict between regulatory jurisdictions and the prospects and limits for regulatory integration, this critical assessment of the trade diplomacy approach to regulatory regionalism must include a comprehensive assessment of the political economy factors shaping the development of domestic regulations.

Given the controversy surrounding the development, commercialisation and international trade of GM crops it is important, at this point, to specify the scope of this study. This study is not a critical assessment of the science of genetic modification. Rather, it is a critical assessment of the social implications of GM crops; specifically the way that this science is promoted and regulated according to the international trade regime and the problems associated with this approach. Moreover, this study adopts four premises. First, the focus of agricultural production must be on achieving greater environmental sustainability while meeting demands for safer, higher-quality products. Second, as the dominant agricultural production system is the intensive agricultural system[1] it is most practical to examine ways to make it more environmentally sustainable. Third, and perhaps most controversial, GM crops can be congruent with a *sustainably intensive* (Sage, 1999) agricultural production system, using for instance, less synthetic chemicals to achieve greater productivity while meeting consumer demands for safer and higher quality products. This does not imply, however, that this study unreservedly supports technological progress over technological precaution. Instead, the fourth premise of this study holds that it is the application, management and distribution aspects of technology that set the parameters for technological precaution and the boundaries for technological progress.

This study is organised into four parts. In Part I is an examination of the issues associated with GM crops. In Chapter One, the academic context of regulatory regionalism is established and the precise research question is specified. The research

[1] The Food and Agriculture Organization (FAO) estimates that up to 95% of global agricultural production is intensive production, as opposed to, say, organic production methods.

methodology employs an International Political Economy (IPE) analytical approach for two important reasons. First, the analysis of *social regulatory barriers* requires an analysis of the 'regulatory arena' (Dezalay, 1996) between the state and the market (Strange, 1988) both within a regulatory jurisdiction, as the domestic regulatory approach is developed, and between regulatory jurisdictions, as regulatory integration occurs. Assessing the regulatory arena requires a multi-disciplinary approach that deliberately combines traditional economic, political, sociological and legal academic approaches to regulations. Second, the analysis of regulatory development and integration requires a simultaneous assessment of the political economy factors within a particular regulatory jurisdiction. As the fundamental objective of an IPE approach is to assess the relative power of various interests and events representing the political economy factors, underlying this critical assessment will be an examination of the 'policy power' or policy influence of various interests in the development and integration of GM crop regulations. It will be argued that these political economy factors can be categorised into either economic or social dimensions – a simple categorisation with significant explanatory power. Contrary to conventional economic approaches that hold the social dimensions constant (Malchup, 1979), it will be argued that it is unacceptable to address *social regulatory barriers* from the economic perspective alone. From a technical point of view, there is a lack of quantitative analytical options. *Social regulatory barriers* are not quantitative trade restriction measures and the economic analysis of regulatory barriers is currently too complex and underdeveloped for systematic economic analysis (Roberts *et al.*, 1999). From a social legitimacy point of view, the predominant calls for *social regulatory barriers* are from non-trade, social interests and not from traditional trade or commercial interests (Perdikis *et al.*, 1999). These non-trade interests view 'social protectionism' as a legitimate constraint on trade liberalisation and they reject attempts to quantify *social regulatory barriers* as economic costs that create social market failures. Instead, they support the notion that regulations play a crucial social function that cannot be decomposed into simply an economic cost. Furthermore, focusing on the interaction between the economic and social dimensions of the regulatory arena avoids the 'trap of institutionalism' (Dezalay, 1996) whereby analysis from one perspective in isolation fails to recognise the belief system that the perspective is based on and which is central to the subsequent analysis. Accounting for the competing belief systems embedded in the economic and social dimensions is to adopt

a 'reflexive methodology' (Bordieu and Wacquant, 1992) that avoids the trap of institutionalism. In Chapter Two is a brief examination of the science of agricultural biotechnology, its application to crop production, the economic implications of this development upon the agricultural sector as well as an examination of the consumer concerns that have created so much controversy. Together, Chapters One and Two establish the conceptual framework for analysing regulatory regionalism created by *social regulatory barriers*.

In Part II, the process of regulatory development and the subsequent challenges of regulatory integration are examined. In Chapter 3 is a discussion of those economic interests supporting the traditional trade diplomacy approach to regulatory development and integration. This includes a comprehensive assessment of how the international trade regime deals with *social regulatory barriers*. In Chapter 4 is a discussion of the regulatory development and integration approaches supported by social or non-trade interests opposed to the traditional trade approach. In Chapter 5 the competing interests are brought together to examine the vociferous debates associated with the development and integration of GM crop regulations. In short, Part II establishes a conceptual model for determining the regulatory framework, the type of specific regulations and, consequently, the regulatory integration approach within an particular jurisdiction.

In Part III is a case study of transatlantic regulatory regionalism. In Chapters Six and Seven, respectively, the North American and the European Union approaches to regulatory development and integration are identified according to the conceptual model developed in Part II. Particular attention is given to the policy power of the competing interests influencing the regulatory development and integration approaches.

In Part IV, Chapter Eight brings together Parts I, II, and III in order to assess why the traditional trade diplomacy approach is incapable of addressing the transatlantic regulatory regionalism associated with GM crops and, hence, stands at a crucial crossroads. Given this analysis, an amended trade diplomacy approach is proposed and examined.

A particularly important methodological issue is the time frame of this study. The critical assessment of trade diplomacy and transatlantic regulatory regionalism includes developments up to June 2000, with the major focus on regulatory development and integration strategies that have emerged in the late 1990s. In other

words, this study is not a critical assessment of a 'closed' trade diplomacy issue. Instead, it is a critical assessment of an 'open' trade diplomacy issue that aims to clarify a complex and controversial challenge that has left trade diplomacy stranded at a crucial crossroads.

Finally, this study makes several general and specific contributions to the academic discourses associated with regulations, international trade and international integration. In general, it contributes to an understanding of the complex challenge that regulatory regionalism and regulatory barriers to trade, especially those driven by social interests, pose to the traditional trade diplomacy approach to international trade and integration. It also contributes to an understanding of the position that various interest groups hold with respect to advanced technologies, regulatory development, regulatory integration and trade liberalisation. Specifically, this study contributes a balanced assessment of a highly polarised issue. It goes beyond the interest-driven rhetoric of both supporters and critics of GM technology in order to identify the root of the controversy and to encourage an informed policy debate over the application, management and distribution of this technology, including the international distribution through trade.

CHAPTER ONE SOCIAL REGULATORY BARRIERS

The objective of this chapter is to locate the challenge of social regulatory barriers to trade diplomacy within an academic context. This chapter is organised as follows. First, social regulations are defined along with their propensity for instability and their trade barrier-aspects. Then the concept of international integration is introduced and an assessment of both the economic and the social perspectives on regulatory development and integration are discussed within this context. Next a theoretical framework identifying the regulatory development and integration parameters faced by a regulatory jurisdiction when dealing with social regulatory barriers is proposed. The chapter concludes with a discussion of the specific case study – the transatlantic trade of GM crops – and the specification of the precise research question.

1.1 Social Regulations: Instability and Market Access Barriers

When discussing regulations, it is important to disentangle regulations from the regulatory framework. The regulatory framework includes the meta-principles and features of the regulatory approach within a jurisdiction. This includes principles such as: which government agency is responsible; is the agency accountable to an elected official or is it an arm's length, independent agency; what are the regulatory principles that regulators must achieve (e.g. safety/hazard prevention only or broader socio-economic development targets); what type of liability laws exist.

Regulations refer to the specific rules developed within the regulatory framework and they are mandatory, legal measures adopted by governments to influence the outcome of economic and social activity within the regulatory jurisdiction, which is often synonymous with the nation-state. Caswell and Henson (1997) argue that regulations can be in the form of either direct regulations or specific liability laws. The former are proactive measures setting the parameters of acceptable behaviour. The latter are reactive measures used to discipline behaviour found to be unacceptable. Together, direct regulations and specific liability laws establish a relevant rule of law within the regulatory jurisdiction. Economic and social activity then occurs within the context of the rule of law.

In a very broad sense, regulations essentially perform two general functions. The first is an economic function such as ensuring the productivity and

'competitiveness' of commercial activity within the nation-state (Porter, 1990). This can include tax measures to stimulate investment in research and development, competition laws to ensure the presence of a competitive commercial environment and employment programs to support worker training and skills acquisition strategically targeted to the competitive needs of the jurisdiction. The economic function of regulations tends to focus on improving the allocative efficiency of the market system. The second general function of regulations is a social function which channels market activity to meet non-market, domestic preferences and expectations. Social regulations include, for example, food safety measures (Spriggs and Isaac, In Press), environmental protection measures (Wheale and Williams, 1996), labour standards (Langille, 1996), as well as measures to address social norms such as moral, ethical and religious concerns. The social function of regulations tends to focus on improving the equity within the jurisdiction. Of course, this categorisation of regulations is simplistic because all regulations are in fact a blend of economic and social objectives. The purpose of this categorisation is, however, to illustrate that some regulations are dominated by efficiency or competitiveness concerns (economic regulations) while other regulations are dominated by equity or non-commercial concerns (social regulations).

The development of a regulatory framework as well as specific regulations within that framework involves building consensus and cohesion through a political process of balancing the rights and interests of stakeholders within the jurisdiction (Picciotto, 1996; Dezalay, 1996). Given the political balance required of regulatory development, once the regulatory framework is set institutional stability is necessary for the rule of law to become established in a manner beneficial to both economic and social interests. Economic benefits of a stable regulatory framework include commercial certainty and predictability. Social benefits include confidence in the regulatory approach. A regulatory framework that changes frequently appears to indicate that regulators lack control, decreasing public confidence in the regulatory approach. In other words, economic and social benefits arise because the regulatory framework is operational and stable.

Accordingly, changing the regulatory framework is not an easy process. It has been argued that institutional inertia makes change difficult and it requires a high-level political push (Frost, 1998). The impetus for such a political push is often changes in the economic and social dimensions of the nation-state. Two crucial causes

are technological innovations and political crises (Dezalay, 1996) and there is a synergistic relationship between them. The public may poorly understand advanced technologies and their development and commercialisation can cause a political crisis as public concern grows about the level of regulatory oversight governing the risks of the new technology. Further, the introduction of advanced technology can set the economic or commercial function of regulations in conflict with the social function. For instance, the innovation may promise economic productivity and efficiency benefits so that economic regulations aim to encourage *technological progress*. In this case, economic regulations are used to set the pace and dispersion of advanced technology (Zilberman *et al.*, 1999). On the other hand, public anxiety about the innovation requires social regulations encouraging *technological precaution* in order to maintain public confidence in the regulatory approach (Kraus, 1998).

While stability may an appropriate goal of the regulatory framework, it is not necessarily the appropriate goal of the precise regulatory rules. For instance, given significant public anxiety about the commercialisation of advanced technologies, flexibility in regulations may be appropriate so that the regulations are seen to be reacting to the anxiety in a publicly acceptable manner. Stability, in this case, may appear to result in regulatory decisions about product approvals that fail to account for social dimensions. Therefore, stability in the regulatory framework is necessary, but the specific regulatory rules may need to be flexible in order to be socially responsive.

1.1.1 Social Regulatory Instability: Advanced Technologies

As mentioned above, the development and commercialisation of advanced technologies such as GM crops is rife with controversial debates that challenge the social consensus of the regulatory framework, motivate political action and result in regulatory instability as the regulatory framework and the subsequent specific regulations are developed and revised.

The common approach to regulating new technology is according to the Risk Analysis Framework. First outlined in 1983, the Risk Analysis Framework seeks to identify procedures to effectively perform risk assessment, risk management and risk communication (National Academy of Sciences, 1983). The objective of this regulatory framework is to establish stable and predictable regulatory principles upon which to base the specific regulations.

Regulatory instability arises because there are significant debates associated with how the Risk Analysis Framework should be applied. The debates reflect conflicts between those who seek to maximise technological progress and those who seek to maximise technological precaution. Establishing a cohesive and consensual regulatory framework is extremely difficult in the face of highly polarised views about the risks of new technologies. These debates as they pertain to the development of GM crop regulations will be examined in greater detail in Chapter 5. It is important to emphasise at this stage, however, that stable framework principles for regulating GM crops have not been established within regulatory jurisdictions, let alone the specific regulations within this framework. Supporters and critics of the technology are actively lobbying government regulators to establish regulations congruent with their views. In reaction, government regulators have been unable and perhaps unwilling to nail down the framework principles that will become the basis for the regulatory Risk Analysis Framework within that jurisdiction. It will be shown (in Part III) that even in jurisdictions with a seemingly established and stable regulatory framework there is evidence of potential regulatory instability.

1.1.2 Social Regulatory Barriers

Unstable social regulations can incur market access barriers during the international trade of advanced technology products because political economy factors such as political processes and the influence of various economic and social interests and events differ between nation-states. As a result, divergent jurisdictions develop different regulatory frameworks such as the Risk Analysis Framework and subsequent regulations can differ significantly. Hence, divergent frameworks create different regulations that can become the basis for market access difficulties faced by foreign products whose production, processing and/or composition contravene the preferences and expectations embedded in the regulatory framework and regulations of the domestic market, despite the fact that these products have been approved in their home market.

In the context of trade barriers, social regulatory barriers represent a new and complex challenge for trade diplomacy. Figure 1.1 provides a categorisation of various types of trade barriers. Trade diplomacy has been successful in reducing tariffs on manufactured goods and in bringing greater discipline on the use of non-tariff barriers such as quantitative restrictions (Jovanovic, 1998e; Grimwade, 1996).

Tariff Barriers	Non-Tariff Barriers		
	Quantitative Restrictions	Regulatory Barriers	
- Tariffs on imported products	- Import Quotas - Voluntary Export Restraints - Anti-Dumping Duties - Countervailing Duties	Economic - Taxation laws - Competition laws - Foreign investment laws	Social - Food safety - Environmental protection - Labour standards - Cultural/normative protection

Fig. 1.1: Classification of Trade Barriers

Yet, trade diplomacy has not been as successful with regulatory-type barriers to trade. Building on the general distinction introduced above between the economic and social function of regulations, there are two types of non-tariff regulatory barriers. Economic regulatory barriers tend to be driven by commercial interests who seek government assistance in competing with foreign firms. In this sense, economic regulatory barriers represent economic or commercial protectionism that is often deliberate and can take the form of, for instance, commercial laws on foreign direct investment and ownership. Alternatively, social regulatory barriers tend to be driven by non-commercial interests such as consumer and environmental organisations. In this sense, social regulatory barriers represent social protectionism. They differ from economic regulatory barriers because often the trade barrier aspect of social regulations is a secondary consequence. That is, social regulations are established to meet domestic social preferences and expectations, although they may also have an impact upon trade flows.

While regulatory barriers in general and some social regulatory barriers in particular are not new to the trade agenda, the depth of food safety and environmental protection regulations into national regulatory competence is a complex challenge for trade diplomacy. For instance, the 1995 Agreement on Sanitary and Phyto-sanitary Standards under the WTO aimed at disciplining the use of food safety-type social regulatory barriers (see Chapter 3). Rather than facilitating an international centralisation of domestic food safety regulations, the Agreement has revealed that social regulations are a formidable challenge to traditional trade diplomacy. In a controversial trade dispute decision the WTO ruled against the European Union (EU) ban on imports of beef treated with growth hormones, yet the EU has not removed the import ban. The key result is that in defence of their social regulatory barriers, the EU

is willing to remain in contravention of the WTO trade regime and this should stand as a vital warning to trade diplomacy efforts.

It is important to disentangle the concepts of social regulatory barriers and regulatory regionalism. Social regulatory barriers are market access barriers facing imported products because the products fail to meet the domestic regulations focussed on social objectives. Specifically, social regulations enacted to deal with GM crops remain unstable and susceptible to influence from all interested stakeholders including the agricultural biotechnology sector and non-governmental organisations such as environmental groups. Regulatory regionalism exists when not only do regulatory jurisdictions differ on specific regulations they differ on fundamental framework regulatory principles underlying the specific regulations. Again with respect to GM crops, there is no internationally harmonised regulatory framework. Instead there are two dominant regulatory jurisdictions - North America and the European Union – with different regulatory frameworks and social regulations. This transatlantic regulatory regionalism has created a trade situation where GM crops approved as safe for food and feed use and for the environment in North America have faced delayed and prohibited market access approvals according to EU social regulations. The key point to make is that while the traditional trade diplomacy approach may be able to deal with social regulatory barriers when the underlying frameworks are congruent, it appears that there are significant challenges posed when the underlying regulatory frameworks differ significantly.

1.2 International Integration

As the thesis of this study is that traditional trade diplomacy cannot adequately deal with the challenge of regulatory regionalism associated with GM crops, the assessment must now identify the traditional trade diplomacy approach along with competing or alternative approaches. Perhaps the most illustrative way of accomplishing this is within the broader context of international integration.

International integration is the dynamic process whereby the economic and social (i.e. political, cultural, normative, etc.) dimensions of a nation converge with those of other nations. International integration occurs regionally (bilaterally or plurilaterally) and globally (multilaterally). Moreover it is a neutral term. For supporters, international integration is predicated on the belief that collective action among individual nation-states can lead to greater overall gains than those possible

when nations act alone. This belief is best exemplified by the mandate of the United Nations; to achieve global stability and security by promoting economic and social development through the co-ordinated efforts of individual nation-states. For critics, international integration is a corrosive force that erodes national economic and social distinctiveness. This study does not aim to address the debate over the efficacy of integration. Instead, it adopts the premise that good or bad, integration is inevitable and the important issue is not about choosing between integration or disintegration but about managing integration in an acceptable manner.

The challenge of social regulatory barriers to international trade diplomacy is in essence a challenge for international integration because trade is really only one aspect of international integration, although a highly visible aspect. As the commercial activities of independent nation-states have become increasingly enmeshed, differences in social regulations have become more apparent. These differences have hindered integration and in some cases have led to calls for greater social protectionism.

A notable characteristic of the academic discourse on international integration is the separation of international *economic* integration from international *social* integration. The basis for the separation is the perspective that is adopted. International economic integration adopts an economic perspective to explain the regulatory development process and the regulatory integration strategies adopted within a jurisdiction. According to this perspective, rational, optimising behaviour should govern policy development, shape social regulations and be the basis for dealing with social regulatory barriers through trade diplomacy. It will be argued that this perspective has been the basis for the traditional trade diplomacy approach. Alternatively, international social integration adopts a social perspective arguing that markets are embedded in social constructs so that the economic perspective is meaningless if separated from social realities. That is, the development of regulatory and trade policies must target more than just an economic function, they must also fulfil important social functions. As a result, the social perspective suggests that trade diplomacy must be more socially responsive when dealing with social regulatory barriers.

Crucially, the economic and the social perspectives on international integration support divergent paths for regulatory development within a jurisdiction and divergent recommendations on how regulations should be integrated between jurisdictions. The

key to understanding the challenge of social regulatory barriers to traditional trade diplomacy is to understand the differences in the two perspectives because essentially trade diplomacy has emerged from the economic perspective while social regulations emerge from the social perspective. Given this crucial disjuncture, these perspectives are discussed in greater detail below.

1.2.1 Economic Perspective: Scientific Rationality

Since at least 1947, the economic perspective has dominated trade diplomacy, which has been a relatively successful example of international economic integration. It has facilitated the development of a rules-based international trade regime characterised by commercial regularity, orderliness and predictability (WTO, 1995), allowing for a substantial growth in global trade flows.

The basis of the economic perspective is that decentralised and distributed decision-making can lead to economically optimal outcomes (Bratton *et al.*, 1996). The key goal of the economic perspective is to improve market efficiency and effectiveness. It aims to deliberately separate economic dimensions from social dimensions in an attempt to de-politicise the policy development process. This removes protected social positions that create social and political market failures hindering the attainment of economically optimal outcomes. Removing social and political market failures allows national policy development to focus on real market imperfections with first-best policies.

This does not imply, however, that social dimensions are sacrificed. Instead, it is held that improved market operations increases growth and development. This in turn, increases income and the demand for social regulations such as food safety and environmental protection because, it is argued, they are income elastic (Caswell, 1997). These income elastic social preferences are internalised by the competitive strategies of private firms because they are demanded by consumers, they enhance the firm's social reputation and they increase investor confidence (Woolcock, 1996). Ultimately economic growth produces improved social regulations; a regulatory race to the top. In short, the economic perspective holds that it is vital to first remove social and political market failures in order to produce the best conditions for economic growth and that this in turn allows for the establishment of optimal social regulations with a tendency to become more stringent, not less.

The economic perspective has been used to assess how regulatory development should occur within a nation-state or regulatory jurisdiction and how regulations should be integrated between jurisdictions. With respect to how regulatory development should occur, public policies in the post-war period were significantly influenced by Keynesian economics and its reliance upon government policy expertise. It suggested that government intervention in the market could secure an optimal outcome that the decentralised market was unlikely to produce (i.e. government intervention preserves a long-term agenda to facilitate the economic prosperity of the nation). Underlying this theory were two important assumptions. First, it was assumed that policy-makers are aware of all economic and social preferences, through the political process, and could design first-best regulatory policies producing optimal outcomes. Second, it was assumed that government policy-makers are benevolent agents whose primary goal is the improvement of national welfare and no other objectives obfuscate this goal. These assumptions did not go unchallenged.

Public Choice Theory challenged the ability of policy-makers to be aware of all economic and social preferences. Samuelson (1954) argued that the political process could not accurately reflect all preferences because the nature of public goods encourages market failure. Voters can either under-represent their utility derived from a public good because they have not had cause to consume the good (Samuelson, 1954). An example might be local fire services. Alternatively, voters can over-represent their utility because they do not know the true cost of public goods (Malchup, 1979), such as food safety or environmental protection measures. Malchup (1979) argued that if the true cost were known then the demand for the public goods would fall.

Similarly, Social Choice Theory also challenged the assumption that government policy-makers could be aware of all economic and social preferences. Arrow (1963) argued that because voting paradoxes prevent the aggregation of all preferences, the preferences that policy-makers target are at best only partial preferences. Further, Olson (1965) argued that the problem lies not just with the voting process because regulators are easily captured by, and respond to, special interests resulting in government intervention in pursuit of only limited objectives, not overall national welfare.

Both Public and Social Choice Theory argued that despite the best efforts of government policy-makers the combination of failures with the political process and the prevalence of regulatory capture result in protected political positions. Without an awareness of all economic and social preferences a true first-best regulatory policy could not be established. In order to correct the policy problems, the Public and Social Choice Theories adopted the economic perspective of de-politicising the policy process by separating the economic objectives of market efficiency from social objectives of equity. Once the market was working efficiently, then optimal levels of social regulations could be established rather than the ex ante establishment of sub-optimal regulations that then hinder market efficiency. Additionally, it was proposed that a subsidiarity or devolution policy be adopted in the regulatory development process in order to decrease the variance in economic and social preferences, decrease the number of special interests lobbying the process and to enhance the link between the regulators and those that the regulations affect. The economic perspective thus supports a competitive decentralisation and de-politicisation of the regulatory development process.

The economic perspective also led to challenges to the second assumption of the Keynesian-type interventionist theories; that government policy-makers are benevolent maximisers of national welfare. Clearly, government does play a more active role including intervening to fulfil its own preferences and objectives. For instance, according to the Constitutional Political Economy approach, Brennan and Buchanan (1980) argued that government regulation is not in pursuit of social welfare. Instead, governments are 'regulatory monopolists'. At the governmental level, the political concerns of re-election dominate long-term economic and social development concerns. Within government, departments compete with one another to secure revenues and preserve regulatory power or authority. In this sense, regulations must be viewed as political instruments created by policy-makers in pursuit of their own self-interest instead of in pursuit of national welfare. In response, it was argued that the economic perspective must be adopted in order to avoid the political market failures caused by governmental self-interest.

With respect to the political crisis driver for regulatory development and change, the economic perspective has little support for a reactive, socially responsive regulatory approach. Instead, it supports a regulatory framework that is de-politicised in order to disentangle political and social market failures from real market failures

(Majone, 1990). Underlying this perspective is the belief that government regulatory intervention adversely impacts economic and social prosperity because it increases market distortions driving up costs and decreasing commercial competitiveness, productivity and market efficiency (Woolcock, 1998). This in turn, decreases economic growth and development and decreases the demand for income elastic social regulations.

With respect to the technological innovation driver for regulatory development and change, the economic perspective generally assumes that technology and innovation are vital factors of economic growth and welfare[2]. As a result, it supports a regulatory framework encouraging technological progress. For instance, it is quite common for economic analysis to support 'scientific rationality' (van den Daele *et al.*, 1997) approaches to regulating the risk of new technology. The economic and scientific rationality perspectives are similar in that they decompose complex behaviour and actions into causal-consequence models, which are then used to forecast outcomes (see Chapter 5.1.1 for further discussion).

In short, the economic perspective on regulatory development holds that an efficient regulation is one that corrects a market failure and improves the resource allocations of the free market encouraging technological innovation and growth. Accordingly, policies must be activated by market failure and focused only on economic factors in order to improve the prospects for economic growth allowing for the optimal establishment of social regulations, free from the distortions of protected political positions.

International economic integration is simply an extension of the national economic perspective on regulatory development to the international level where the nation-state, as the regulatory jurisdiction, remains the primary actor. The rationale for international economic integration is to facilitate scale economies and the optimal allocation of factors of production according to comparative advantage (Jovanovic, 1998e). The principle of comparative advantage is simply the principle that national welfare can be maximised by allocating factors of production to where they are most efficiently utilised and then trading the products to meet consumer demand. A division of the factors of production is widely accepted as an organising principle at

[2] It is important to note that while this is a widely established economic tenet, not all economists hold this view. For an insightful discussion of the 'steady-state' or 'zero-growth' economy see Daly (1997).

the national level and comparative advantage extends this notion to the international level (Malchup, 1979).

From the perspective of international economics, trade barriers hinder market access and distort comparative advantage. They fragment international markets, limit economies of scale, increase costs and create market access uncertainty. In fact, economic trade analysis considers barriers to be 'economic costs' placing distortionary constraints on a firm's production function and collectively, on a nation's production possibilities frontier. Such analysis focuses on the cost, price and allocation effects of trade barriers in order to demonstrate their impact on comparative advantage and economic welfare.

Economic trade analysis has long shown comparative advantage to be a compelling argument for non-discriminatory, liberalised trade because it results in the optimal and efficient allocation of production and consumption patterns. Indeed, international economic integration literature generally assumes that any type of economic integration is positive (Grimwade, 1996). However, debates exist regarding the level of economic integration that is most optimal in terms of national welfare. For instance, Jovanovic (1998a,b,c,d,e) assesses the economic benefits of and limitations to greater economic integration at a regional (bilateral or plurilateal) and global (multilateral) level.

As mentioned above, international economic integration has been the foundation of trade diplomacy since at least the establishment of the General Agreement on Tariffs and Trade (GATT) in 1948. Trade diplomacy according to the economic perspective aims to separate economic integration from social integration in order to disentangle political and social market failures from real market failures. According to the WTO, the goal of trade diplomacy (based on the international economic integration perspective) is to develop multilateral rules to remove social and political protectionism; to de-politicise trade and make it a function of comparative advantage not political advantage (WTO, 1995). The threat is that political and social market failures would become locked-in to the regulatory approach, preventing the identification of an optimal regulatory standard and hindering economic integration, innovation and growth (Arthur, 1989; David, 1987; Katz and Shapiro, 1986).

Further, the economic perspective holds that economic integration does not imply a loss of sovereignty or policy autonomy. It is argued that international trade treaties or agreements represent concessions by all signatories in order to realise

mutually beneficial gains from economic integration (Jovanovic, 1998e). In this sense, there is no loss of policy sovereignty as all signatories or contracting parties have given up the exact same degree of autonomy. For example, in discussing the impact of the Canada-US Free Trade Agreement on Canadian sovereignty, Lipsey (1988) concluded, "Canada can establish and maintain its own distinctive social policies, while liberalising its trading arrangements with other countries". In other words, economists tend to argue that economic integration and trade liberalisation do not result in an absolute loss of domestic policy autonomy vis-à-vis other countries.

It should be noted, however, that the discussion on the economic perspective is not to suggest that social dimensions have never factored into the economic analysis of integration. Indeed, both Cooper and Massell (1965) and Johnson (1965) introduced a 'public good' rationale for regional economic integration whereby economic integration permitted the increased production and consumption of public goods. Also, agricultural economics has often adopted a view of economic integration where social dimensions have played a primary role in trade policy development. For instance, popular social arguments for supporting and protecting domestic agriculture include strategic arguments of ensuring a domestic food supply and 'multifunctionality' arguments claiming that the agriculture sector not only produces food but that it also provides social benefits in the form of the protection and preservation of the countryside and the rural lifestyle. Political economy models of tariff determination have been developed to cope with the agricultural sector's social protectionism (Frey, 1984; Frey, 1985). The key point, however, is that the analytical focus is on determining the effects of the social dimensions on economic efficiency, hence, the economic perspective not the social perspective dominates.

With respect to regulatory regionalism, there are two fundamental trade concerns about the impact of social regulatory barriers upon traditional international economic integration. First, social regulatory barriers are seen as an easy target for protectionist rent-seekers because there is virtually no discipline on their use under international trade rules. Second, income elastic social regulatory barriers could fragment international markets into exclusionist social regulatory jurisdictions that hinder multilateral economic integration and, consequently, limit the gains from trade. Therefore, to deal with these concerns the economic perspective advocates that social regulatory barriers be subject to multilateral economic integration rules according to the traditional trade diplomacy framework of the WTO – a method that has been

successful in (discussed further in Chapter 3). That is, the barriers should be subject to an economic interpretation of efficiency, they should have a minimum trade impact and trade diplomacy should avoid considering social arguments for the trade barriers.

The regulatory integration approach supported by the economic perspective is one of regulatory competition associated with the 'free traders' school of trade theory (Bhagwati and Hudec, 1996). The regulatory competition paradigm rejects efforts to co-ordinate or harmonise, ex ante, national regulations because regulatory differences are considered to be a basis for comparative advantage and trade opportunities (Lavoie and Sheldon, 1999). For instance, income elastic social regulations such as food safety and environmental protection would be different among trading partners at different levels of economic development. Yet, this may create a comparative advantage and gains from trade for firms in jurisdictions with a different regulatory framework. In other words, this paradigm supports national sovereignty or authority over regulatory policy because of the belief that distributed regulatory development enhances both commercial opportunity and social welfare. Accordingly, it favours shallow international integration based on the economic perspective with no aim to develop international social and political institutions other than those necessary to facilitate a rules-based regulatory framework for international economic integration.

Over time, international regulatory competition may produce ex post regulatory integration where either the market decides which approaches are optimal or a trade dispute mechanism determines which approaches are permissible from the perspective of a rules-based regulatory framework designed to promote international economic integration. Alternatively, the regulatory competition paradigm may not produce regulatory integration and regulatory divergence would prevail.

Therefore, with respect to social regulatory barriers, the economic perspective suggests that regulatory development should focus on technological progress and market efficiency while regulatory integration should focus on economic integration according to the regulatory competition paradigm. The result is support for a rules-based regulatory framework ensuring stability, orderliness and predictability during the process of international economic integration. With respect to the international trade of GM crops, this would take the form of an international regulatory framework focused on technological progress and market access with very little regard for social dimensions in the regulatory process beyond fundamental principles such as safety or hazard.

1.2.2 Social Perspective: Social Rationality

Competing with the economic perspective on regulatory development and integration is the social perspective. Fundamentally, the social perspective reverses the causation between market performance and social objectives. The social perspective insists that underlying the 'market' is a normative construct composed of domestic preferences, concerns and expectations (Bratton *et al.*, 1996). This normative social construct, including moral, ethical and religious concerns, cannot be separated from the market because social norms organise market operations. Consequently, the social perspective holds that neo-classical economic policies do not represent an independent ideal but rather a set of policies congruent with a neo-liberal normative social construct. Without this construct, these economic policies would not be appropriate. Hence, the social perspective posits that economic policies are crucially constrained by the normative social construct.

According to the social perspective, the development of a regulatory framework within a nation-state is not simply an exercise in correcting market failures. Instead, regulatory development also plays a more important social function in channelling the economic activities of the nation-state to achieve normative social development objectives identified through the domestic political process. In this sense, social responsiveness is the main driver for regulatory change where regulators are expected to react to social dimensions such as political crises in an accountable manner. Underlying this view is the belief that government regulatory intervention improves economic and social prosperity because it increases public participation and accountability improving productivity and competitiveness (Woolcock, 1998).

Regulatory effectiveness is assessed according to whether or not regulations successfully respond to legitimate social concerns such as equity as opposed to whether or not they meet economic measurements of efficiency. From the social perspective, it has been argued that the economic perspective leads to a 'hollowing out' of the nation-state (Picciotto, 1996) whereby social dimensions are sacrificed to enhance economic performance.

With respect to the technological innovation driver for regulatory development and change, a popular socio-political treatment of the social perspective may be found in Risk Society Theory (Beck, 1992) and its extensions (i.e. Grove-White *et al.*, 1997), which focus on the regulation of risk, such as the risk from new technology.

This 'social rationality' approach holds that it is insufficient to view new technology and innovations only as a positive force in economic growth. Instead, the social implications of science must be considered and under this consideration new technology may not always be greeted without reservation – despite its potential to improve economic growth. For instance, Habermas (1971) cautioned that the scientific complexity of advanced technologies erodes the established political process because it has rendered elected decision-makers nothing more than "mere agents of a scientific intelligentsia" as policy decisions are made about new technologies outside democratic accountability and in pursuit of economic objectives only. The social rationality approach argues that it is the social dimensions, such as the application, management and distribution of the technology that are most crucial in deciding whether or not a new technology is necessary. Hence, the general tendency is to support regulations which encourage technological precaution and which are capable of responding to broader social concerns about new technology beyond just the potential economic benefits (Beck, 1992). Contrasting the two perspectives then, the social perspective supports social rationality and technological precaution over the scientific rationality and technological progress supported by the economic perspective.

With respect to the international integration of regulations, a key concern of (but not limited to) the social perspective lies with the impact of integration upon the policy autonomy of the nation-state – as the primary regulatory jurisdiction – to support its own unique normative social construct. Does international integration strengthen or weaken the sovereignty and authority of the nation-state? With respect to the former, it has been argued that increased integration is not necessarily an internationalisation of the nation-state, but rather a domestication of the international arena; strengthening the social authority of the nation-state (Hanreider, 1978; in Picciotto, 1996). This comes about because integration is based on a shared normative social framework (Milward, 1992), possibly promoting a regional or even global normative framework (Global Governance, 1995). On the other hand, it has been argued that the social authority of the regulatory jurisdiction is eroded as nation-states accept limits on their power (Dezalay, 1996; Picciotto, 1996) and adopt an increasingly top-down framework reflecting the economic perspective, unaccountable to the domestic political process and insensitive to the unique political economy factors of particular regulatory jurisdictions (Giddens, 1985).

Given the ambiguous impact of integration on the policy autonomy of the nation-state it is important to assess the social rationales for integration, that is, why would international integration be supported at all? A fundamental rationale is the 'neo-functional' rationale, which posits that integration promotes interdependence, and can facilitate broader global stability and security objectives (Frost, 1998). To achieve this goal, economic and social integration are promoted by policy networks (Keck and Sikkink, 1994), epistemic communities (Haas *et al.*, 1992) and by an emerging global civil society (Lipschutz, 1992).

Another rationale to pursue deeper social integration is to address social externality issues or 'regulatory universals' (Dezalay, 1996), such as food safety and environmental protection. Social externality issues are those whose impact is felt beyond the borders of the nation-state. Food products are widely traded and it is common for a consumption bundle to include foreign produced goods. Similarly, environmental degradation ignores political boundaries and often has international consequences. Social integration is proposed as a method for ensuring that the externalities created in a foreign jurisdiction but which impact the domestic jurisdiction are dealt with rather than left to the forces of international economic integration. This can include methods to enhance the co-ordination of divergent food safety and environmental protection regulations among regulatory jurisdictions. It is important to note that the implication of defining social externality issues or regulatory universals is that it fragments social regulations into two categories. The first is, of course, the social regulations addressing externality issues. The second is social regulations addressing exclusively domestic normative preferences such as moral, ethical and religious concerns. The importance of this categorisation of social regulatory barriers is that social externality regulations are more likely to be internationally integrated than exclusively domestic normative social regulations. Hence, it is important to identify the type of social regulations causing the regulatory barriers when assessing the propensity for integration.

An important aspect of the social perspective is that it generally supports either a deeper regulatory integration between nation-states than that supported by the international economic integration approach or no integration at all. This support is rooted in an increasingly popular dichotomy suggesting that a nation-state can pursue either greater international economic integration through liberalised trading arrangements or it can pursue stringent domestic social regulations, but not both

(Garvey, 1995). That is, this dichotomy views these objectives as mutually exclusive where increased trade liberalisation must produce decreased social regulatory protection. It views economic integration only as a negative, corrosive force that imposes market competition upon non-market, social dimensions. Further, it is argued that because non-market, social dimensions are improperly valued in the economic perspective, international economic integration leads to a social regulatory race to the bottom (Drache, 1996).

The reason for this negative view is that the social perspective does not consider the international economic integration approach of trade diplomacy to be de-politicised. On the contrary, it is argued that the economic integration is in fact a highly interventionist form of governance which imposes neo-liberal economic policies onto national governments for the benefit of only a minority of international capitalist entrepreneurs (Dezalay, 1996). Further, it puts social polices beyond the authority of domestic governments (Langille, 1996). It has been argued that the international trade regime represents subversive liberalism (Rhodes, 1994), symbolic imperialism (Dezalay, 1996), and global unilateralism (Strange, 1986; Whitman, 1984) of the neo-liberal economic perspective.

The social perspective's rejection of international economic integration creates a propensity to support social protectionism; regulatory regionalism based on social values and concerns where jurisdictions cluster together to fend off the influence of international economic integration. Two general implications of social regulatory regionalism may be identified. First, in order to establish a regional regulatory integration approach Winters (1994) argued that the block must adopt the most precautionary position of the most hesitant, anti-integrationist member. This implication is especially important when considering integrating the various regulations for the risks of new technologies. Second, as social regulations are income elastic, regulatory regionalism is inherently exclusionist as it excludes less developed countries without the same level of income (Wang and Caswell, 1997). In short, it has been argued that social regulatory regionalism represents social protectionism that represents a stumbling block for multilateral regulatory integration.

In order to deal with social regulatory barriers and to develop a global or regional normative framework, the social perspective proposes that a co-ordinated approach to regulatory integration must be employed. The regulatory co-ordination strategy of integration is associated with the 'fair traders' school of trade theory (van

Scherpenberg, 1998). This strategy supports ex ante bilateral, plurilateral or multilateral efforts to level the social regulatory playing field. This is predicated on the belief that centralised regulatory approaches enhance welfare by explicitly addressing social dimensions rather than leaving them to the forces of economic competition. Crucially, regulatory co-ordination is a conciliatory or cooperative approach to overcoming divergent social regulatory barriers emphasizing shared objectives and establishing social regulatory floors – preventing a regulatory race to the bottom. If deeper social integration cannot be pursued, then the social perspective supports a rejection of international integration based only on regulatory competition. For instance, the proposed Multilateral Agreement on Investment in 1998 and the launch of a round of trade negotiations at the WTO Ministerial 1999 in Seattle were prevented in part by the influence of social interest groups who refused to support an integration agreement that was limited to international economic integration only.

In short, the social perspective suggests that regulatory development should focus on technological precaution and social responsiveness according to a social rationality approach, while regulatory integration should pursue social integration according to the regulatory co-ordination paradigm. The result is the creation of a socially rational approach to the international regulation of social externalities such as food safety and environmental protection.

1.2.3 Regulatory Development and Integration

An important similarity between the two perspectives discussed above is that the nation-state retains social regulatory autonomy or sovereignty. Yet, Table 1.1 reveals crucial differences between the economic and the social perspectives. The economic perspective supports regulatory development and integration focused on economic market efficiency and technological progress through a de-politicised and de-centralised process of international economic integration through regulatory competition. The social perspective supports regulatory development and integration based on social principles of meeting non-market public preferences, expectations, concerns and fears.

The challenge of social regulatory barriers to traditional trade diplomacy emerges because the economic perspective has dominated trade diplomacy while the social perspective dominates social regulations such as food safety and environmental protection regulations. Given that the trade diplomacy challenge is to reconcile the

economic and the social perspectives, the objective now is to examine ways to encourage a stable regulatory framework and an effective regulatory integration strategy that appropriately acknowledges the social dimensions of the social regulatory barriers.

	Economic Perspective	Social Perspective
Regulatory Development	Scientific rationality approach	Social rationality approach
	Focus: correcting market failure	Focus: social responsiveness
	Technological progress	Technological precaution
Regulatory Integration	Economic integration	Social integration
	Regulatory competition	Regulatory co-ordination

Table 1.1: Comparison of Economic and Social Perspectives

With respect to developing a stable regulatory framework and subsequent regulations, a jurisdiction must find some way to balance the scientific rationality approach of the economic perspective and its calls for technological progress, with the social rationality approach of the social perspective and its calls for technological precaution. Can the Risk Analysis Framework be used to achieve this balance? Despite the polarity between the two perspectives, it will be argued that the scientific rationality and the social rationality approaches may be integrated to form an effective Risk Analysis approach. Beck (1992) argued "scientific rationality without social rationality remains empty, but social rationality without scientific rationality remains blind". Building on this position, this study will explore ways to employ the Risk Analysis Framework in the development of GM crop regulations in a manner that effectively acknowledges the competing interests and balances technological progress with technological precaution.

With respect to creating an effective integration strategy that accounts for both the economic and the social perspectives, a regulatory jurisdiction faces three integration parameters (Fig. 1.2). First, the regulatory jurisdiction must establish the level of integration to be pursued; regional (bilateral or plurilateral) or global (multilateral). Second, the regulatory jurisdiction must choose the depth of integration to be pursued; shallow economic integration or deeper social integration. Third, the regulatory jurisdiction must choose what type of integration or convergence strategy to pursue; the regulatory competition approach or the regulatory co-ordination approach. The various integration approaches along with some examples of each are summarised in Table 1.2.

1. Integration Level

	I. Global/Multilateral	II. Regional/Bilateral or Plurilateral

3. Integration Strategy

2. Integration Depth		Regulatory Competition	Regulatory Co-ordination
	Shallow 'Economic' Integration	A	B
	Deeper 'Social' Integration	C	D

Fig. 1.2: Integration Parameters of the Regulatory Jurisdiction

There are two crucial and interrelated domestic factors influencing the integration approach adopted the regulatory jurisdiction. First, the traditional regulatory role of the state will influence the regulatory framework developed (Woolcock, 1998) and this influences the integration approach pursued. Generally, if the regulatory tradition is closely associated with the economic perspective, then it is likely that shallow economic integration based on regulatory competition will be the preferred approach (area A in Fig. 1.2). In contrast, if the regulatory tradition is closely associated with the social perspective, then it is likely that deeper social integration based on regulatory co-ordination will be the preferred approach (area D in Fig. 1.2).

Second, competitiveness of the jurisdiction is important or in other words, the integration approach is case specific. If, for instance, the regulatory jurisdiction enjoys a commercialisation lead and competitive advantage in a particular regulatory area, then it is likely that they will have well-developed regulations which domestic firms have already internalised so that the regulations of other jurisdictions will not be difficult to comply with. In this case, it is likely that the regulatory jurisdiction will support international economic integration according to regulatory competition. Alternatively, if the regulatory jurisdiction is at a commercial lag or competitive disadvantage vis-à-vis other jurisdictions it may be unlikely that it will have regulations well-developed enough to deal with the influx of advanced foreign technologies. In this case, it is likely that the regulatory jurisdiction will support social integration according to regulatory co-ordination as protection from the new technology and the competitive foreign products.

A	Aim is to facilitate economic integration according to the national treatment principle in order to allow decentralised market activity to achieve economically efficient and optimal outcomes. This is the approach employed in international and regional economic analysis of customs unions and free trade areas (Grimwade, 1996; Jovanovic, 1998 a-e).
	I: Multilateral: The traditional trade diplomacy framework exemplified by the GATT/WTO trade regime.
	II: Regional examples include: Association of South-East Asian Nations Free Trade Area (ASEAN FTA); North American Free Trade Area (NAFTA), Caribbean Economic Community (CARICOM); the former European Free Trade Area (EFTA); Mercad Comun del Sur (MERCOSUR); and the 1995 proposal for a Transatlantic Free Trade Agreement (TAFTA).
B	Aim is to facilitate economic integration (multilateral or regional) by co-ordinating divergent regulations in order to develop a common framework, thus removing market failures and access barriers and allowing decentralised markets to achieve economically efficient and optimal outcomes.
	I: Multilateral examples include the WTO Agreement on Sanitary and Phyto-sanitary Measures which attempts to remove domestic regulatory barriers for food safety by co-ordinating regulations within international standards-setting organisations such as the Codex Alimentarius (see Chapter 3.2.1.C).
	II: Regional examples include: the EU-US Transatlantic Business Dialogue (TABD) 1995 which is a forum for commercial interests to identify regulatory barriers; the Canada-EC Framework Agreement for Commercial and Economic Co-operation 1976; and the EC-Canada Trade Initiative (ECTI) 1998.
C	Aim is to transform the market to 'internalise' or appropriately value traditionally non-market, social objectives so that decentralised market activity can achieve efficient and optimal outcomes.
	I: Multilateral examples include: academic literature food economics (Spriggs and Isaac, In Press; Caswell, 1999; Perdikis *et al.*, 1999; Caswell and Henson, 1997), environmental economics (Siebert, 1991: Paul, 1996; Swanson, 1997), labour standards (Langille, 1996)
	II: Regional examples include: academic literature on corporate law (Carney, 1996; McCahery and Bratton, 1996; Romano, 1996) and the New Transatlantic Marketplace (NTM) initiative 1995 and the follow-up Transatlantic Economic Partnership (TEP) initiative 1998 which outline a transatlantic commitment to liberal market objectives as a stepping stone for multilateral integration.
D	Aim is to develop a global or regional normative social construct through co-operative, ex ante co-ordination of domestic economic and social regulations.
	I: Multilateral examples include: the overall mandate of the UN; the UNEP's Biosafety Protocol (Isaac and Phillips 1999a,b and see Chapter 4.2); Multilateral Environmental Agreements such as the Kyoto Protocol and the Basel Convention on Hazardous Waste (see Chapter 3.2.2.A); and efforts of international organisations including the International Labour Organisation (ILO).
	II: Regional examples include: the EU Eco-Labelling Scheme (Isaac and Woolcock, 1999); the Transatlantic Consumers Dialogue (TACD) 1998; the Transatlantic Environmental Dialogue (TAED) 1998; the proposed 1995 EU-US Transatlantic Treaty; the Transatlantic Declaration on EC-Canada Relations 1990; and the EU-Canada Joint Political Declaration and Action Plan 1996.

Table 1.2: Summary of Integration Parameters: Approaches and Examples

Clearly, there is a synergistic relationship between these two factors. A regulatory jurisdiction may enjoy a commercialisation lead because its traditional regulatory role supported technological progress and this technological progress may have brought tangible benefits that encouraged a regulatory framework even more congruent with technological progress. Moreover, as a result of these two factors there is a path-dependency aspect of the development of a regulatory framework and the

subsequent support for a regulatory integration strategy. The various political economy factors (i.e. the economic and social interests) within a regulatory jurisdiction establish a trajectory for the regulatory framework that determines the type of regulatory integration strategy that can be adopted. Deviating from this trajectory can be very difficult.

The integration approaches and examples summarised in Table 1.2 are generalisations because, in reality, it is difficult to find a regulatory integration example that fits entirely into each category. Perhaps the most illustrative example is the regional integration of the European Union (discussed in greater detail in Chapter 7). The EU-style regulatory integration, set out in the 1985 White Paper on the Single European Market (European Commission, 1985), pursues both economic and social integration according to a blended strategy of regulatory co-ordination and regulatory competition (Woolcock, 1996). In fact, the EU-style integration straddles IIC and IID in Fig. 1.2.

Yet, despite its generalised nature, this conceptual model of integration is useful in capturing the complexity of the task of addressing social regulatory barriers. It reveals that traditional international trade diplomacy (IA in Fig. 1.2) is actually only a very narrow approach to regulatory development and integration that deliberately omits a significant array of issues and concerns raised by social regulatory barriers; especially its omission of the social perspective. As social regulatory barriers are inextricably linked to the social perspective and to the regulatory development process, this omission is completely unsustainable.

1.3 Social Regulatory Barriers: A Case Study

This research examines this fundamental shortcoming of traditional trade diplomacy through a case study of a current and complex issue – the transatlantic trade of GM crops. This case study represents the conflict between the economic and the social perspectives on regulatory development and integration. The thesis is that social regulatory barriers can only be addressed through a regulatory integration strategy that acceptably accounts for the social perspective driving the development of social regulations. In other words, in order to remain a viable force in international integration, trade diplomacy must be amended. Yet, this study also goes beyond just comprehensively identifying a problem. In Chapter Eight, it also brings together the previous sections in order to propose a trade diplomacy approach that, although

reaching deep into areas of national competence, is congruent with a stable, operational and socially acceptable regulatory framework capable of overcoming regulatory regionalism and social regulatory barriers to trade.

CHAPTER TWO AGRICULTURAL BIOTECHNOLOGY

Modern biotechnology represents very sophisticated technological innovations at the frontiers of science embedded with economic and social implications. It involves techniques capable of altering the functions and characteristics of living organisms. As its application across medical, pharmaceutical, chemical, forestry, fishery, environmental and agricultural uses is rapidly growing, the potential economic implications of modern biotechnology upon the industrial landscape are enormous. Specifically, modern agricultural biotechnology has already been used to alter the function and characteristics of agricultural crops and considerable research is underway aimed at applying the techniques to an increasing range of agricultural crops. Yet, while applications in other sectors have been readily accepted, agricultural biotechnology has been controversial.

The objective of this chapter is to define what is meant by 'genetically modified' agricultural crops, to describe both current and future applications and to assess the factors that have made the consumer acceptance of GM crops controversial. There are two important caveats. First, this description is not intended as a comprehensive introduction to biotechnology (see Grace, 1997; Ho, 1998; Krimsky and Wrubel, 1996; McHughen, 2000; Wartburg and Liew, 1999). Second, the science is discussed to the extent necessary to provide background to the regulatory policy debates involving various interest groups within regulatory jurisdictions.

2.1 Modern Biotechnology and Agricultural Crops

Although this study is focused on the social implications of science, it is necessary to provide a brief description of the science of modern agricultural biotechnology because it is clear that there is a broad ignorance of what genetically modified (GM) crops are, and perhaps more importantly, what they are not. While every effort is made to keep this section brief an understanding of GM crops is a crucial prerequisite for any credible assessment of appropriate regulatory approaches.

2.1.1 The Science

Attempts to enhance the desirable characteristics of agricultural crops and to limit the expression of undesirable characteristics have always been an objective of agricultural production (Kenney, 1986). These attempts developed into sophisticated

techniques of plant breeding with the result that highly specialised crops were developed to meet a diverse range of human needs and ecological conditions. Although successful in developing increasingly useful agricultural crops, plant-breeding techniques were time-intensive and plant breeders lacked the specific knowledge of how characteristics were really expressed in the crops. As a result, there was a significant degree of uncertainty in the trial and error approach to varietal development. For instance, the hybridisation of corn through traditional plant breeding took 20 years and involved several iterative steps (Harlander, 1993). First, two parental varieties with desirable characteristics were crossed to produce seeds. The off-spring were then grown-out in field trials to identify those plants that expressed the desired characteristic, while those that did not were discarded. Next, the desirable off-spring were back-crossed with the parents to further isolate the desirable traits. This trial and error approach to traditional plant breeding continued until a desired hybrid variety was produced.

Modern agricultural biotechnology is differentiated from traditional plant breeding techniques because it combines the knowledge of the role of genetics in the expression of characteristics with the techniques and procedures capable of modifying the genetic make-up in order to modify the characteristics. This is primarily the role of molecular and cellular biology where the former is "the study of DNA" and the latter is "the study of the structure and function of living cells" (Barton, 1998).

The key to genetic modifications is that all organisms interpret DNA in the same way. In this sense, all organisms are related (Office of Technology Assessment, 1984; Barton, 1998). However, sexual compatibility for the most part limits genetic transfer. Traditional plant breeding techniques, such as the hybridisation of corn, attempted to isolate the expression of desirable characteristics by controlling the sexual reproduction of crops. Modern biotechnology allows plant breeders to isolate and control genetic traits at a much more specific level. The term genetic modification (GM) has been used widely to refer to all biotechnologies, there is, in fact, an important distinction. In genetic modification, the DNA of an organism is altered so as to produce some desired result but no 'foreign' DNA is added. In transgenic modification, DNA is actually transferred between organisms. Sequences of DNA are isolated in an organism, using techniques of molecular markers, and cut from an organism using restriction enzymes. These enzymes recognize certain sequences of DNA according to their nitrogenous bases. Once the pieces of DNA are cut from an

organism, they then must be pasted into the DNA of another organism. There are three techniques for importing and pasting specific pieces of DNA (Fincham and Ravetz, 1991). The first technique is employing a bacteria vector, such as the common *Agro-bacterium* technique where desirable DNA is pasted into the bacteria, which then transfers inside the target cell. Similar in operation is the second technique, employing a virus vector. The disease symptoms and infectivity material of the virus are removed, but not its function for initial infections and replication. The third technique, is a vectorless technique, such as the 'gene-gun' where tungsten bullets coated with the desirable DNA are shot into the target cell. In contrast to the sexual transfer of the entire genetic blueprint all at once, as in traditional plant breeding, transgenic modifications can be quite precise and can circumvent the sexual compatibility limitation (Cape, 1986). Following the standard practice, genetic modification (GM) will be used synonymously with transgenic modification unless otherwise specified.

When the genetic modification is complete, other biotechnology techniques may be employed to assist the development of the genetically modified organism, such as tissue culture techniques and gene mapping or gene tracking techniques (Fincham and Ravetz, 1991; Harlander, 1993). Tissue culture techniques are essentially a conventional practice of traditional plant breeding, but with some improvement. The cells, with the transgenic modification are cultured into seeds and contained growth trials are performed to assess the viability of the transgenic variety. This is followed by controlled field trials performed to assess whether or not the transgenic variety expresses the desired characteristics. Gene-mapping and gene-tracking techniques allow plant breeders to identify if the desired transgenic modification is present in the target cells and seeds without having to grow out the seeds in field trials (Barton, 1998). One common, but controversial method is to use an antibiotic resistant marker gene to identify the desired genes. Cells are cultured in an environment of antibiotic, and only those that survive would have retained the gene[1]. Gene-mapping both decreases the need for field trials and, hence, decreases the risk of release of unwanted transgenic varieties because the desired traits will be identified in the seeds prior to the field trial.

[1] Fincham and Ravetz (1991) argue that although the antibiotic resistant marker gene has been the most widley used, it is not the only gene-mapping technique available. Others include polymerase chain reaction (PCR) technique and Beta-glucuronidase (a blue pigment for 'visual' mapping)

The point is that modern biotechnology is really a package of techniques allowing for the varietal development of agricultural crops at a more precise and perhaps more controlled level than ever before. It is a process or production technique with the power to alter conventional genetic processes creating GM varieties of traditional agricultural crops or creating novel GM varieties never before characterised.

This is not to say that there is no uncertainty with these techniques. Indeed there still exists considerable uncertainty with gene functions yet this uncertainty exists with traditional plant breeding as well. Modern biotechnology, however, offers the plant developer far more control over varietal development than that possible with traditional plant breeding techniques because the genes are known to the scientist and can be tracked in the cells of the GM crop. In fact, due to this precision, it has been argued that transgenic modifications are safer and more controlled than traditional plant breeding techniques which manipulate the entire genome of the parents, rather than just specific genes (van den Daele *et al.*, 1997; Harlander, 1993; Hullar, 1993).

2.1.2 Current and Future Applications of Agricultural Biotechnology

The application of modern biotechnology to agricultural crops can generally be categorised into three types: production trait applications, output trait applications, and applications to create Bio-Engineered products (Brenner, 1998)[2]. These three categories will be described below. The first type of application is currently the most widespread while applications to output trait applications or Bio-Engineered products are indicative of the future of GM crops.

Production trait applications of agricultural biotechnology represent a scientific response to long-standing agricultural problems, which had traditionally been addressed through domestic agricultural support programs. Agricultural production has always been a risky venture, characterised by a significant degree of possible variation in crop quantity (yield) and quality each year. The risks to the quantity and quality of agricultural production are from the weather (i.e. drought,

[2] Other categorisations include: D. Zilbermann *et al*, (1997), 'Agricultural Biotechnology: Economic and International Implications' (Sacramento: Contributed Paper, XXII Conference of IAAE) supply-enhancing, pest-control, quality-modifying, new products; and S. Shimoda (1997), 'The Biotechnology-Driven Transformation of Agriculture', (Sacramento: Contributed Paper, XXII Conference of IAAE) input traits, output traits, performance traits. Although different, these categorisations indicate that modern biotechnology can either enhance conventional traits or create wholly new ones in agricultural crops.

floods, hail, and frost), from soil conditions (i.e. salinity, nitrogen depletion, and erosion), from disease (i.e. rot, fungal and rust), and from pests (i.e. bacteria, virus, nematodes, insects and animals). In both North America and Europe, various and financially significant domestic support policies are employed to stabilise the agricultural sector in the face of this risk.

GM crops provide scientific solutions to agricultural production risk through attempts to improve the production traits of agricultural crops. For instance, new GM varieties of conventional crops have been created (or are being developed) with a higher degree of stress tolerance to ecological conditions and with a higher degree of resistance to pests and disease.

Two of the most common production trait modifications are herbicide tolerance and insect resistance, traits which are targeted for the intensive agricultural system. With respect to herbicide tolerance, GM crops have been transgenically modified with a gene found in a soil bacteria that is able to metabolise (digest) the non-selective, broad spectrum herbicide glufosinate, rather than be destroyed by it (Moschini *et al.*, 1999). With respect to insect resistance, several agricultural crops such as corn and cotton have been transgenically modified to express the pesticidal characteristics of *Bacillus turingiensis* (Bt), a soil micro-organism that produces a protein toxic to certain insects (Harlander, 1993).

Production trait applications were the most common GM crops up to the 1999 crop season (James, 1997; 1998; 1999). It has been estimated by Monsanto that global production of GM crops will involve over 98.5 million acres. Of these applications, most are single-trait stacking modifications whereby the genetic material for, say herbicide tolerance, is transferred creating a GM variety that is herbicide tolerant. The two most frequent single-trait stacking modifications were for herbicide tolerance and insect resistance. However, multi-trait stacking modifications represent the future of production trait GM varieties (Brenner, 1998). That is, transferring the genetic material for, say herbicide tolerance, insect resistance and virus resistance, to one plant organism creating a GM variety that simultaneously expresses the three desired traits. At the same time, new agricultural crops will be subject to production trait applications. Therefore, production trait applications will both deepen, with multi-trait stacking, and widen, include new crops without current GM varieties.

There are two important aspects of production trait applications. The first is that they do not require the adoption of new agronomic practices or farm implements.

They can be produced within the traditional agricultural production system, although they may require changes in the chemical regimes. The second is that since the end-attributes of the GM varieties remain the same or 'substantially equivalent' to conventional non-GM varieties, they are both for the same end-use and sold into the same processing and distribution system as non-GM varieties and it is virtually impossible to distinguish between the two in the agricultural distribution system. In short, production trait GM crops have been developed to fit into the traditional agricultural commodity supply system.

The second broad type are output trait applications targeting those commercial characteristics of the crop that determine its value, in order to increase value by increasing the expression of the desirable characteristics. Improving crops to enhance value may be viewed as a scientific response to the problem of crop quality. GM varieties of crops are being customised to meet the specific demands of end-users, such as livestock feeders, food processors or industrial users, who may place a premium on high quality products. High quality characteristics include improved nutritional content (i.e. protein and oils), flavour, or the functionality of the crops such as delayed ripening or rotting. Functionality can also include enhanced processing characteristics such as ease of separation of fibres, oils, starches, sugars and proteins (Brenner, 1998), where increased processing ease would translate into decreased energy requirements.

Similar to the production trait applications, output trait applications do not require the adoption of new agronomic practices or massive investment in new agricultural implements. These varieties may be produced according to traditional agronomic practices. Unlike production trait applications, they do require changes in the distribution of agricultural commodities. These varieties have end-attributes that need to be differentiated from the conventional varieties in order to capture the value premium. Output trait applications create incentives for more active management of the crop distribution system through segregation. However, this degree of specificity is not yet part of the supply-chain. In fact, in North America, improved output traits made up less than 1% of total acreage of GM crops in both 1997 and 1998 (James 1999), in part because the bulk nature of the agricultural commodity distribution system makes it difficult to ensure segregation between the desired varieties and other varieties without some sort of price premium.

The third broad type of agricultural biotechnology application is to create Bio-Engineered products. Brenner (1998) suggests that with Bio-Engineered products "the power of sunlight and plant physiology are harnessed to replace expensive chemical synthesis processes". Such applications would have industrial uses far beyond traditional agricultural products. Yet, Brenner (1998) also notes that such applications demand a level of biotechnological sophistication much more advanced than the current generations of single- and multi-trait stacked GM varieties.

Bio-Engineered GM varieties would be entirely novel, rather than just improvements to conventional varieties. For instance, in the pharmaceutical sector, such applications, known as 'pharming', would allow agricultural crops to be used as bio-factories producing high-value pharmaceuticals or edible vaccines that are currently produced using relatively expensive chemical synthesis processes, decreasing the use of chemicals. As well, agricultural biotechnology may be employed for high-tech nutritive fortification of foods designed for health care and disease prevention, essentially becoming nutriceuticals. For instance, a current research initiative involves the transgenic modification of potatoes with Cholera B toxin. Consumption of the novel GM product creates the production of human cholera resistance antibodies. Other edible vaccines include GM crops with enhanced cancer fighting anti-oxidants, probiotics and prebiotics. Another example is the nutritionally enhanced Vitamin A GM rice developed to address the serious Vitamin A deficiency in Thailand and other South-East Asian countries. Finally, an entirely industrial application of agricultural biotechnology would be the creation of plant-based polymers replacing petroleum-based polymers currently used in synthetic fibres, plastics and even fuels (Brenner, 1998). An example of this is a plant based credit card developed by Monsanto and endorsed by Greenpeace in Europe as an alternative to plastic credit cards (Globe and Mail, 1998). The potential benefit is the creation of completely bio-degradable polymers[3].

Unlike production or output trait GM varieties, Bio-Engineered products would require substantially different agronomic practices. Also, to ensure that such crops grown for industrial non-food uses are kept out of the food supply, Bio-

[3] Even one the most ardent critics of modern biotechnology, Jeremy Rifkin, views this potential contribution as beneficial. "The biotech age...holds great promise: a cornucopia of new plants and animals to feed a hungry world...and new genetically engineered sources of energy and fibre to propel commerce and build and 'renewable society'" (Rifkin, 1998).

Engineered products would require an effective segregation and identity preservation production system.

Despite the potential of output trait applications and Bio-Engineered GM products, there are limits to what agricultural biotechnology can achieve. For instance, it has been argued that "no scientists will be able to take a tomato, add 20 genes from a cow and 30 genes from wheat, and come up with a crop that has the nutritional qualities of beef and bread."(Brill, 1988 in Wiegle, 1991). Further, the challenge facing crop developers is not how to prevent GM crops from getting out of control, but rather, how to develop GM crops that are viable enough to grow within the agricultural system – the very same problem that faced traditional plant breeders as well.

This brief examination of the current and future applications of agricultural biotechnology has revealed several important features. First, it appears that agricultural biotechnology is, in fact, poised to deepen and broaden its impact upon economic production. Second, it has been revealed that agricultural biotechnology and rDNA techniques represent another phase in the knowledge-intensification of agricultural production. Third, it has also been revealed that current applications of agricultural biotechnology are not significantly novel applications. Instead, they are more modest applications, incrementally made and very much in keeping with the systematic varietal development process characteristic of plant breeding.

From the point of view of regulatory policy development and integration there are four important distinctions to identify. First, not all *genetic modifications* are *transgenic modifications*. From a plant perspective, transgenic modifications, as discussed above, involve the transfer of genetic material between plants or other organisms. However, some modifications, such as antisense modifications[4] and mutagenesis[5], only alter the genetic material within a plant's cell in order to achieve desired results, therefore there is no transfer of genetic material. It appears that the greatest opposition to *genetically modified* crops is actually directed at *transgenically modified* crops where genes from sexually incompatible organisms are combined. It is

[4] From Harlander (1993); antisense modifications involve 'switching-off' the function of certain genes within the organism's genome in order to produce desired affects e.g. the ripening genes in Monsanto's FLAVR SAVR tomato had been selectively inactivated.

[5] From Harlander (1993); mutagenesis involves exposing seeds to a mutagenic agent (ethylmethylsulfonate or EMS) and then growing seeds out to select those resultant plants with desired traits. In this case, the genetic modification is a more random or imprecise process than transgenic

important to disentangle *genetic modification* techniques from *transgenic modification* techniques because not all biotechnology applications are associated with those concerns that are really only relevant for *transgenic modifications*[6].

The second important distinction is between a GMO and a living modified organism (LMO). A LMO is a sub-set of GMO in that it is a GMO that retains metabolic activity. For an example consider GM canola/rapeseed. As a seed, it is both, technically, a GM seed and a LMO because it remains capable of propagation. Crushed into canola oil it is no longer capable of propagation and is no longer a LMO, yet it remains a derivative of a GM crop in the strictest sense (see the discussion on the Biosafety Protocol Chapter 4.2).

Third, GM crops are not always 'novel' plants. Novel plants, known as plants with novel traits (PNTs) are those for which a naturally occurring counterpart does not exist. PNTs may be created either through the use of biotechnology or through traditional plant breeding techniques. Hence, novel does not imply the use of biotechnology. GM crops do, however, imply the use of biotechnology since they have been genetically modified, although not every genetic modification creates a PNT. For instance, if genetic modification is used to develop a new corn variety from two parental varieties, then the resultant GM corn is not novel, in the sense that it does not express traits never before characterised in corn varieties. Instead, it simply has enhanced corn traits that have been combined from the parents.

Fourth, and arising from the third distinction, GM crops do not always produce GM foods. For example, the oil and lecithin of oilseeds such as soybean and canola are used widely in food processing, however, oil and lecithin do not contain DNA or protein. So, although they may be derived from GM varieties, they do not contain GM material and subsequent foods produced with these inputs are not GM foods. This distinction is made clear by an examination of the difficulties of testing a food ingredient or product for GM material (Hanley and Johnson, 1999). From a technical, testing perspective a researcher can either test for the GM DNA sequence or the presence of the introduced protein encoding for GM DNA. In the former, the test is accurate but sophisticated and time-consuming, as the investigator must know exactly what GM DNA sequence to look for. In the latter, the test is rapid but less

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modifications with the deliberate environmental release of less well characterised plants, yet this method has not been controversial.

sophisticated and less accurate as it relies upon the binding of an antibody to the introduced protein. The problem is that food processing easily breaks down the protein and can also degrade the DNA to the point where it can no longer be identified as a GM food. In fact, foods which have been processed (e.g. heated, fermented, acidified, extruded, or highly refined) generally have no GM DNA left in them or at least highly degraded GM DNA. If the GM DNA was no longer in its unique sequence encoding for the particular protein then there is no risk that a consumer is ingesting a harmful protein resulting from the genetic modification. An exception, of course, is crops that are eaten raw or unprocessed, for example, GM maize or GM tomatoes. In these two examples, the GM crops would produce GM foods. The point is that with the exception of foods eaten raw or unprocessed the general term 'GM foods' is often applied inaccurately and inappropriately.

The four distinctions are important in considering how to appropriately regulate GM crops. For instance, if public concern really lies with the transfer of genes between sexually incompatible organisms – transgenic modification – then regulations should target TGM crops, not all GM crops. If it is plant novelty that is the concern, then novel-based regulations are more appropriate than technology-based regulations. If the concern lies with the protein structure of genetically modified organisms, than the focus should only be on those products that still contain the GM DNA sequences. The distinction between GM crops and LMOs is crucial because, as will be discussed in Chapter 4.2) the Biosafety Protocol is an international treaty governing the transboundary movement of LMOs. Yet, unless GM crops are shipped in seed form and capable of propagation then they should not fall under the regulatory principles of this protocol. Therefore, understanding these important distinctions is vital in establishing regulatory approaches that respond to actual consumer concerns rather than approaches built on vague, ambiguous fears about a misunderstood application of modern agricultural biotechnology techniques.

2.2 Agricultural Biotechnology: An Overview of Consumer Acceptance

To this point the application of modern biotechnology to agricultural crops has been examined as a scientific, technological innovation that promises to have vast implications upon agricultural production. Yet, at the most basic conceptual level all

[6] For an example of a failure to disentangle this important distinction see Sheppard (1997) where the concerns really only associated with transgenic modifications are cast across all GM techniques.

production is for consumption and some consumers have not accepted GM because they remain unconvinced about the consumer benefits or because they have concerns or fears about the technology.

Consumers are not just economic agents but also social agents who vote and participate as citizens, ultimately shaping the national social and political context within which, economic forces operate. For instance, venture capitalists may not be willing to fund GM crop developers if it would be publicly unpopular[7]. Similarly, producers may be unwilling to plant GM crops if either they cannot market them or if they will be vandalised by eco-warriors. More importantly, however, consumers have enormous influence over the research, development and commercialisation of GM crops primarily through their influence upon regulatory approaches. Therefore, a critical assessment of the social implications of agricultural biotechnology must focus on the issue of consumer acceptance and its role in shaping the domestic regulatory approach and the nation's regulatory integration strategy.

The objective of this section is to identify the predominant issues associated with the consumer acceptance of GM crops because these issues are cited by various interests groups active in the regulatory development process. While the issues are presented here in a descriptive fashion they will be the basis for assessing the economic (Chapter 3) and the social (Chapter 4) interests influencing GM crop regulations.

2.2.1 Agricultural Biotechnology and Consumer Concerns

There are four types of consumer concerns: economic concerns, human health and safety concerns, biodiversity concerns (including animal, plant and environment health), and moral, ethical and/or religious concerns. A synergistic relationship exists between the four types of consumer concerns. They may be positively related and mutually reinforce a particular consumer position. Inversely, they may be negatively related, forcing the consumer to strike a balance between benefits on the one hand (i.e. lower price or improved nutritive content) and costs on the other (i.e. a moral perception that genetic modification is unnatural or wrong).

[7] In 1999, Deutsche Bank Europe predicted that biotechnology firms will become a 'pariah' of shareholders and will suffer an 'earnings nightmare', while GM crops will be a liability for farmers. Also, the Public Ledger (No. 72,139 25 October 1999) reports that Monsanto's shares have slumped from a high of $US 51 in may to $US 38 in October 1999 because of shareholder concerns about consumer attitudes.

Economic Concerns

Economic consumer theory presents consumers as economic agents, driven by the principle of non-satiation, who consume normal goods based upon the attributes of the goods and subject to a budget constraint. The attributes of the good, price and quality, are relative variables that assist the consumer in choosing the consumption bundle which maximises consumer welfare or utility. Much economic analysis is focused on the price to determine the cost/benefit to consumers from the use of GM crops. If the use of a GM crop reduces the relative price of a normal good, then according to economic consumer theory, the consumer will choose to consume more of that good and, subsequently, consumer welfare or utility is increased through the use of GM crops (Hoban, 1996; Moschini *et al.*, 1999). Similarly, if the use of GM crops leads to increase in the price of that good then consumer welfare or utility is decreased (Giannakis and Fulton, 2000).

Economic consumer concerns may also involve concerns about the broader economic impact of GM crops, which may positively or negatively influence acceptance. For instance, a high concentration of research capacity providing well paying high-technology jobs and creating economic spill-over, may enhance the perception that GM crops are associated with wider economic benefits. Similarly, improvements in productivity and income among the rural sector may also be considered by consumers to be an economic benefit, positively influencing consumer acceptance. Inversely, the broader economic impact of GM crops may negatively influence consumer acceptance. Three examples are illustrative of this. First, consumers may view GM crops as facilitating the further industrialisation of agriculture and being socially destructive because of the economic displacement of rural communities[8]. Second, they may perceive that all the economic benefits are accruing to the large private multi-national firms developing GM crops or to farmers, with no benefit to consumers from the new technology. Third, economic consumer concerns may be associated with the potential economic impact of GM crops used for import substitution upon developing countries.

Human Safety and Health Concerns

[8] Cited by Britain's Prince Charles as a negative aspect of agricultural biotechnology (London Times, 29 October 1998).

Apart from economic concerns, consumers are concerned about the human safety and health implications of GM crops. Human safety concerns refer to the short-term absence of illness immediately after consumption, while human health concerns refer to the longer-term health implications such as cumulative nutritional impacts. Essentially, the fear is that genetic modifications will result in toxigenic, pathogenic, infective, or invasive changes to the plant affecting human safety and health. Also, a secondary human health concern associated with GM crops arises from the use of antibiotic resistance genes in gene-tracking procedures. It is a secondary concern because although there are no direct consequences on human safety or health from consuming such marker genes, the concern is that their use will increase the incidence of antibiotic resistance in bacteria that are harmful to humans. Such concerns negatively impact consumer acceptance.

Yet, GM crops with improved nutritional characteristics, such as the Cholera B potato or the Vitamin A rice can have positive impacts upon public health and may enhance consumer perception of agricultural biotechnology. Further, GM crops eliminating or reducing the need for herbicides and pesticides would have significant impacts upon human safety, health and various allergies and sensitivities.

Biodiversity Concerns

There are also consumer concerns associated with the potential impact of GM crops upon biodiversity, which can positively or negatively influence consumer acceptance. From a biodiversity point of view, a current international focus is on sustainable development[9], which for agricultural purposes translates into sustainable agricultural production techniques. While GM crops can have negative impacts on sustainable agriculture and biodiversity, they can also have positive impacts (Bonny, 1999).

Biodiversity concerns involve the perception that GM crops will result in toxigenic, pathogenic, infective, or invasive changes producing aggressive crops that disrupt the ecosystem. For instance, one argument suggests that the transgenic modifications could transfer to either conventional non-GM varieties of the same plant (the so-called invasion of origin concern) or to non-target plants and organisms

[9] The Brundtland Report defines sustainable development as 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs' (WCED, 1987).

through vector mediated horizontal gene transfer and recombination. It has been argued that genomes are dynamic and predisposed to incorporate foreign DNA (Wheale and McNally, 1990). In fact, some observers have made dire predictions of genetic pollution, habitat destruction and destabilisation of entire ecosystems brought on by aggressive GM crops (Ho, 1998; Rifkin, 1998). Other biodiversity concerns are associated with the fear that farmers producing herbicide resistant GM crops will apply herbicides in a reckless, irresponsible fashion in an attempt to control weeds, harming biodiversity (Consumers' Choice Council, 1999)[10]. Such concerns negatively influence consumer acceptance of GM crops.

With respect to the potential biodiversity benefits of GM crops it has been argued by many supporters that the future of GM crops is essentially chemical-free production congruent with sustainable farming trends. Agricultural production free of herbicides, pesticides and fertilisers would have enormous benefits on biodiversity. GM crops, tailored to meet the ecological conditions of various regions could increase the range of alternative crops and crop varieties that producers could choose to plant. This development would break the trend of mono-cropping and result in increased biodiversity. As already discussed, the techniques of gene-mapping and gene-tracking can provide greater control over crop development and effectively limit the number of field trials required to determine if the phenotypic characteristics are present or not. Further, GM crop developers are exploring ways to lock-in or turn-off the transferred genes in GM crops to prevent genetic drift. Such developments should positively influence consumer acceptance of GM crops.

Moral, Ethical and Religious Concerns

The acceptance of GM crops is associated with moral, ethical and religious concerns because it involves the modification and manipulation of the processes of life. Survey evidence from both North America (Einseidel, 1997) and from Europe (Eurobarometre, 1997) suggests that consumer acceptance of modern biotechnology broadly and GM crops specifically, is significantly influenced by perceptions of the

[10] See also the comments of Britain's Prince Charles (London Times, 29 October 1998) which seems to reveal a contradiction. On one hand he argues that the farmer is the responsible steward of the land, while on the other, he argues that farmers cannot be trusted with herbicide tolerant crops because they will apply herbicide in a reckless fashion. However, in general this particular concern about the abuse of herbicides does not seem very robust for two reasons. First, herbicide use is a significant input cost for producers who will *always* seek to minimize this cost instead of over-spraying in a reckless fashion.

moral and ethical aspects of the applications. Acceptance is found to be positively associated with those applications that are perceived to be morally beneficial. The Eurobarometre (1997) study concluded that;

> *first, usefulness is a precondition for support; second, people seem prepared to accept some risk as long as there is a perception of usefulness and no moral concern; but third, and crucially, moral doubts act as a veto irrespective of people's views on use and risk.*

Further, with respect to religious concerns, the Eurobarometre (1997) survey evidence has revealed that nearly 40% of respondents believe that religious authorities should be involved in the public policy discussions and decisions regarding biotechnology applications. While North American survey evidence has revealed that acceptance of agricultural biotechnology is negatively related, in part, to religious concern (Hoban, 1997).

The morality and ethics of the application of GM technologies to agricultural crops is also called into doubt because of the scientific rationality approach being pursued primarily by the large multinational Life Sciences firms. In the past, scientists, through the peer review structure of scientific investigation and disclosure, have been trusted to protect social norms in the face of new technology on behalf of the general public. Ho (1998) argues that the shift from public leadership in research on biotechnology to private leadership is associated with several substantial normative problems. First, the scientific research by private firms is 'reductionist' in nature, that is, it employs specific transgenic modifications to a variety and only assesses impact upon that crop. It fails to assess the impact of the GM crop upon the biological system in which the crop operates; a so-called inclusionist approach. Second, the reductionist science supports a false dichotomy between science, as non-negotiable laws of nature, and technology, as the application of science. According to this dichotomy, science is value-free and only when it is applied as a technology does any associated normative issues emerge. This dichotomy is challenged by the argument that science is only a tool for understanding nature and the scientific research is inseparable from social norms and morals. Third, the reductionist, profit-seeking motives supporting the science – technology dichotomy fail to address the public interest since science and

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Second, in most cases, the wealth of the producer is embedded in the agricultural land and it is unlikely that the producer will recklessly jeopardize that wealth.

technology are pursued outside the public debate (often protected by proprietary claims). Only when the technology is to be commercialised is the public interest considered. Indeed, it has been argued that the profit-motive means that private scientists can no longer be trusted to act in a moral or socially ethical manner (Monbiot, 1995). This argument implies as well that the national economic drivers to develop an internationally competitive agricultural biotechnology capacity means that government regulators cannot be trusted either. Accordingly, the result is GM crops without public consent.

Others argue, however, that having moral or ethical concerns about GM crops is a luxury enjoyed by North American and European consumers and made possible by an ample and well-distributed food supply. It has been queried whether it is more unethical to gene transfer or to allow starvation in less developed countries where the choice is not between GM crops or non-GM crops based on moral concerns but between living and dying (Sahai, 1997). Similarly, it has been argued that it is "irresponsible and immoral for the well-fed to spearhead fear-based campaigns and suppress research for ideological and pseudo-scientific reasons" (Prakash, 1999). In addition, an 18-month study by a working group of the Nuffield Council (the leading UK body on bioethics) concluded that there was, in fact, a moral obligation to continue to develop GM crops because of their significant potential[11]. It concluded that there were no grounds for a ban on GM crops because they were not sufficiently different from conventional, non-GM crops and, hence, do not raise moral objections if conventional crops do not. Similarly, the Vatican's Pontifical Academy for Life stated that the use of GM technology in agricultural crops should not raise moral alarm because the advantages are greater than the risks and that the Academy does not agree with those organisations who argue that GM crops are against the will of God (AgraFood Biotech, 1999).

An important feature of the four types of consumer concerns is that they tend to reflect a concern about the *application* of modern agricultural biotechnologies for specific uses, rather than a concern about the technology per se. This is vital in determining what type of regulatory approach is needed: a process/technology-based

[11] See also MAFF. 1993. 'Report of the Committee on the Ethics of Genetic Modification and Food Use (London: MAFF) which concluded that there was no overriding ethical objection of genetic modification in relation to the food chain, including the use of human genes in food production.

approach or a product/application-based approach. These issues will be discussed further in Chapter 5. The important point to make is that GM crops are inextricably linked to a broad range of public concern. The question now is: how is consumer acceptance linked to these concerns?

2.2.2 Consumer Information, Trust and Choice

The four types of concerns represent consumption parameters in the sense that consumers require these concerns to be addressed prior to making a consumption decision. The objective now is to examine the events involved in the acceptance of advanced technologies such as GM crops.

Neo-classical economic consumer theory assumes that consumer concerns are completely addressed through the provision of information. According to the Rational Choice Model, the consumer has access to perfect information about all of the attributes of the products including information about the inputs, the processing and production techniques as well as the costs per unit to produce the good. Implicitly then, the consumer also has access to all the information necessary to address the other consumer concerns, beyond just economic concerns.

Access to perfect information allows the consumer to make rational[12] consumption choices, creating consumer sovereignty. Consumer sovereignty is the notion that the consumer is the best judge of the ramifications of consumption upon consumer concerns, and does not require market interventions to enhance judgment. A consumer may be rational even without perfect information, provided the consumer chooses to be partially informed. The consumer may choose this because, for instance, the time, effort or cost required to gain complete information is not justified by the perceived benefits of being fully informed. In this case, the consumer is boundedly rational (Williamson, 1987). Generally, bounded rationality requires that the consumer trusts the partial information being provided. This suggests an important relationship between information, trust and choice. Essentially, "trust can be a functional substitute for knowledge" (Eurobarometre, 1997) in making either complete or boundedly rational consumption decisions, and consumer sovereignty depends upon the retention of choice.

[12] The concept of 'rational' is subject to interpretation. For instance, Rayner (1992) argues that it is a subjective term. Here it is used in the economic sense, as the efficient allocation of resources according to optimising behaviour.

Are agricultural biotechnology products congruent with the Rational Choice Model of consumer theory? Do consumers have access to all the information necessary to make rational consumption decisions? Do consumers trust the information providers? Do consumers always retain choice? The answer to each question is no and, hence, recent negative consumer reaction to the commercialisation of GM crops should come as no surprise.

Consumer goods may be categorised into three types (Tirole, 1988). First, search goods, are those goods where consumers can visually identify all product attributes prior to purchase and consumption. With search goods all information about the good is effectively transferred from the producer to the consumer. Second, experience goods, are those goods where the consumer isn't able to identify all product attributes prior to purchase and consumption. There is a partial breakdown in the transfer of information from the producer to the consumer at the time of purchase. Yet, the consumer can gain the necessary information through consumption experience. Third, credence goods, are those goods where the consumer is not able to know the full attributes of the product before or after consumption (Bureau *et al.*, 1997; Purchase, 1997). With credence goods there is a total breakdown in the transfer of information from the producer to the consumer; an information gap. Yet, because of consumer trust in those developing the goods (i.e. in scientists), there is 'credence' associated with them.

At the present time, GM crops are credence goods (Isaac and Phillips, 1999). Defining GM crops as credence goods is intuitive since there is a large information gap between producers and consumers. This is due to two factors. First, many consumers do not understand the scientific techniques and procedures of modern biotechnology. In fact, general knowledge about genetics is often lacking among many consumers, let alone specific knowledge about transgenic modifications to agricultural crops. For instance, a recent report by the European Commission revealed that two-thirds of those surveyed did not realise that non-GM tomatoes also have genes or DNA in them[13]. Second, with the dominant role of the private sector, much information may be deemed proprietary and not available to consumers. Further since the research and development that underlies the application of modern biotechnology

[13] European Commission report published in January 1999, reported in the Financial Times (15 March 1999). Given such a lack of understanding of GM crops, it is remarkable, for instance, that Patrick

is advancing rapidly, the information gap, created by the credence nature of GM agricultural crops is likely to widen, not narrow.

The credence nature of goods may be remedied through the provision of information permitting credence goods to shift to experience and then search goods. Evidence in the US has shown that increasing consumer information about GM crops has positively influenced consumer acceptance (James, 1997). An important element of information is transparency as was shown in a recent referendum in Switzerland where consumers/voters were asked about their position on the continued support of biotechnology research and development. Consumer support and acceptance rose as the industries applying biotechnology adopted the strategy of opening up their activities to the public. Eventually, referendum results revealed that two-thirds of 'informed' voters supported the continued research, development and application of biotechnology (European Federation of Biotechnology, 1998). However, transparency has not always been the chosen strategy of both supporters and critics of agricultural biotechnology, resulting in a dual lack of transparency (Economist, 1998). Both sides have, at times, failed to be completely transparent about the opportunities and risks, exacerbating the information gap and consequently, the credence nature of GM crops.

Yet, simply providing transparent information will not remedy all consumer concerns. The information must be useful but there are, however, several challenges to providing useful consumer information. First, providing all the information necessary for consumers to completely understand agricultural biotechnology is impossible given the scientific sophistication of agricultural biotechnology. Consumers would soon experience an over-load of information (Chess, 1998; Eurobarometre, 1997; Hoban, 1997). This occurs because there are important limitations to the consumer's ability to process information. For instance, labels cannot be expected to convey all the information that consumers may want. Indeed, it has been argued that simply labelling a product as 'genetically modified' is meaningless because consumers want to know more contextualised information such as which genes have been used (Grove-White *et al.*, 1997). Consumers must then rely upon the judgement of others and this gives rise to the second challenge, who should provide the useful information?

Without first hand knowledge of the consumption ramifications of GM crops, consumers must trust that their concerns are being adequately addressed by either the

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Holden of the the UK-based Soil Association describes consumer rejection of GM crops as based on 'informed public opinion' (Independent on Sunday, 3 October 1999).

industry, regulators or by a third-party. In both North America (Hoban, 1997) and Europe (Eurobarometre, 1997; Grove-White *et al.*, 1997) consumers have indicated that they most trust third-parties with information about GM crops, especially environmental organisations at the international level. Trust is a delicate attribute of information providers, as it is hard to build but easy to lose (Chess, 1998). However, opinions are very diverse ranging from those who believe in the global welfare promise of GM crops to those who wish to see the technology completely abandoned. The polarity of opinions producing overly sensationalised information can leave consumers very confused.

The third challenge of providing useful information is determining who the information should target? Essentially, is it practical to try to inform every consumer, or is it more practical to target information to a few, who can disseminate it to many? It has been argued that "instead of trying to educate the public, we should focus our attention on the media, health professionals and other opinion leaders" (Hoban, 1996). This position recognises that information must be accessible for the concerned consumer, and these are the information channels that they are most likely to turn to when seeking information.

A further problem remains for consumer acceptance of GM crops. Even if trusted information providers satisfactorily inform consumers, consumers may still lack consumer choice or 'informed consent'[14]. For instance, the global handling and distribution system for agricultural crops is a bulk-oriented system that involves co-mingling of different varieties of the same crop and co-mingling of different crops. Within this existing system, it is virtually impossible to ensure segregation of production improved GM varieties from non-GM varieties. In order to ensure segregation dedicated handling and storage facilities must be used, resulting in cost increases. In fact, due to a purely economic decision, GM varieties approved as substantially equivalent to non-GM varieties were initially co-mingled in the food supply in both North America and Europe without effective segregation and labelling.

With respect to the decision not to segregate, GM crop developers in both the North American and the European grains and oilseeds industry, argued two main points. First, the GM crops had been approved as safe and substantially equivalent to non-GM varieties, so there were no safety reasons to segregate. Second, it was argued

[14] See also Balk (1993) for a discussion of consumer choice, referred to as 'Informed Consent'.

that the distribution system made it virtually impossible to segregate, with zero tolerance, GM from non-GM crops without significant economic costs, a view shared by both US and European industry participants[15]. Economic studies concluded that the costs of segregating would be substantial. An experimental identity preserved production (IPP) system for GM canola varieties was implemented in Canada in 1995 and 1996. From this experiment, it was concluded that an IPP system created incremental costs of between $C 34-37/Metric Tonnes for grains and oilseeds (Manitoba Pool Elevators, 1997). Other estimates concluded that developing and implementing an international IPP system would require a commodity price rise of between 140-180% (EuropaBio, 1997). In this sense, the decision not to segregate GM crops was not taken as a cunning strategy to push GM crops into the North American and European food supply. Instead, it was made on the basis of the economic cost of developing an effective IPP system and with the view that such rises in crop prices and, subsequently, food prices could not be absorbed by the industry and consumers.

Regardless of the industry's intentions to keep prices down at a competitive level, the current controversy surrounding the segregation issue is indicative of the danger of treating consumers as mere economic agents and failing to address their broader concerns.

The biotechnology industry currently faces another important decision associated with consumer information and choice, this time over labelling. Again, the stance of industry and shared by Canada and the US is that, since labelling is not for safety reasons, economics should determine what type of labelling prevails. They argue that certifiably non-GM crops and food products should bear a voluntary label in pursuit of niche market-premiums. Consumers' organisations, however, unanimously support labelling of any use of GM crops in the production of food products as a consumer right to know issue. For instance, 98% in Canada, 85% in the US, while in aggregate 74% of EU consumers have indicated that they want GM labelling even if the GM crop has been approved as safe[16]. The issue of labelling will

[15] See: Agrevo (Nov. 1997); GAFTA, (May 1997); Central Soya, (Dec. 1996); NOPA, (Dec. 1996); ASA, (Dec. 1996) and Sparks Companies, (Sept. 1996).

[16] Based on survey summaries found at Consumers International (1999) General Surveys on Foods Produced Through Biotechnology (www.oneworld.org/consumers//campaigns/food/codex/survey0499.html). In particular: Canada: Toronto Star Poll (2 June 1998) 'Public Prefers Genetically Modified Foods to be Clearly Labelled'; U.S.: Hoban and Kendall (1992) 'Consumer Attitudes about the use of Biotechnology in Agriculture and Food Production' Report to USDA Extension Service; EU: Biotechnology and the European Public Concerted Action Group (1997), 'Europe Ambivalent of Biotechnology: A Commentary', 387 *Nature*, 845-847

be discussed further in both Chapter 3 and in Chapter 5 but the important point to make is that despite the negative consumer reaction to the decision to ignore the broader concerns and only focus on the economic issues of segregation, it appears that some countries are willing to make the same mistake again over the labelling issue.

The discussion above demonstrates the synergistic relationship between consumer acceptance and information, trust and choice. Even if consumers are willing to accept only partial information about credence GM crops and trust the regulators and information providers, the bulk nature of the global handling and distribution system for agricultural commodities restricts or prevents choice when segregation cannot be ensured. In this case, the consumer is unable to make even a boundedly rational consumption decision because of the absence of choice. Furthermore, this does little to ease consumer concerns. On the contrary, the credence nature of GM crops coupled with the inadequate information, lack of trust and absence of choice plays directly into consumer fears and rejection.

2.2.3 Asymmetrical Consumer Acceptance

Further complicating the assessment of consumer acceptance is the existence of discernible differences in consumer acceptance both across biotechnology-based products and between North American and European consumers.

Asymmetry of Consumer Acceptance Across Biotechnology Products

The asymmetry of consumer acceptance across biotechnology-based products is associated with two factors. The first is the consumer's perception of the 'primary beneficiary', while the second is the consumer's perception of control over the application. According to these two factors, modern biotechnology has been more accepted when applied to medical and pharmaceutical industries relative to agriculture[17]. Medical and pharmaceutical applications of biotechnology are clearly perceived by consumers to be focused on human health, therefore the consumer is the primary beneficiary. When the consumer is the primary beneficiary, there is a greater likelihood of acceptance of the benefits and the risks (Slovic, 1987; 1990). On the other hand, GM crops with production-improved traits developed to increase yields and productivity are perceived to create supply-side production benefits only. In this

[17] See: Eurobarometre (1997); Hoban (1997); Economist (1998); Eisseidel (1997); and Hullar (1993).

case, consumers are being asked to accept something that seemingly provides them with no benefits. Medical and pharmaceutical applications are also perceived to be done in controlled research facilities while the field testing and commercial release of GM crops is perceived to be uncontrolled in the environment (Hullar, 1993). Some argue, however, that the difference in acceptance of pharmaceutical or medical applications over GM crops is also related to the fact that in the former, there is a long history of stringent pre-market approval processes while in the latter, food is not traditionally pre-approved in the same fashion (Horton, 1997). This implies that consumer acceptance is also related to regulatory approval.

Even within the broad spectrum of agricultural applications of modern biotechnology there are asymmetries in acceptance. For instance, agricultural applications to improve human health through nutritive fortification are more readily accepted than applications to improve the commercial attributes of produce (Economist, 1998). An example of a GM crop with direct consumer benefits is the development of a GM sugar beet at the Centre for Plant Breeding and Research, Wageningen, Netherlands. Researchers claim that they have developed a sugar with low caloric value because the fructans have been modified to be long-chain fructans which are not easily digested by humans. Interestingly, this GM sugar beet was not given the label 'Frankenstein Food' in the UK media as other GM crops have (Metro, 8 June 1999). In addition, North American survey results indicate that respondents are more likely to accept genetically modified fruits and vegetables than genetic modifications to livestock (Chess, 1998). This indicates that consumer acceptance is linked to perceptions of the morality or ethics of genetically modifying so-called higher-order organisms such as animals (Eurobarometre, 1997; Einseidel, 1997)[18].

The asymmetrical consumer acceptance across products appears to indicate an important principle; that it is the product-application that matters to consumer acceptance, not the technology per se.

Asymmetry of Consumer Acceptance Across Regions

The asymmetry of consumer acceptance across regions is a particular challenge to the international trade and market access of agricultural biotechnology products because regulatory integration efforts must acknowledge regional

[18] For a comprehensive discussion of moral and ethical problems of genetically modifying animals see Fox (1990).

differences. Essentially there are no universal consumer concerns. Instead, they are shaped by historical, cultural and economic conditions (Hoban, 1997). Additionally, consumer concerns are also influenced by the current information consumers receive. For instance, in the UK GM crops have been inaccurately portrayed as an 'American' technology or 'Monsanto's' technology (Ecologist, 1998)[19], despite the fact many European firms are highly active in the GM crop development along with European universities and public research institutes[20]. Therefore, the complicated mix of consumer concerns and asymmetries of acceptance across products must additionally be understood within a regional context. The focus of the analysis will be on asymmetries in consumer acceptance between North American and European consumers.

Broad support for modern biotechnology is greater in North America than in Europe. Hoban (1997) reports that between 66 and 75 percent of survey respondents in the United States indicated acceptance of biotechnology products, yet in Europe, the acceptance among respondents is just over 50%. Although North American acceptance is evidently higher than in Europe, it is important to note that this acceptance was not unconditional. In fact, concern over the use of recombninant bovine somatotrophin (rbST) in dairy cows in the US a decade ago is very similar to current European concern and action regarding the use of GM crops in the food supply. At the forefront of rbST concern, was the US-based Foundation for Economic Trends (Wiegele,1991). Due to the public concerns many industrial dairy farms refused to use rbST in their herds. As well several large food processors (e.g. Kraft USA, Borden Inc., Dannon Inc.) along with many food retailers (e.g. Kroger, Safeway, Pathmark, Stop & Shop, Vons) all boycotted milk and milk products produced from rbST herds. These boycotts remained in place until the scientific uncertainties surrounding the use of rbST had been addressed in a sufficient way to reduce consumer concerns.

To deal with the asymmetry in consumer acceptance of GM crops, both Monsanto and the European biotechnology industry association EuropaBio launched public information campaigns in 1998 in an attempt to increase European consumer information about the benefits of GM crops and, hence, increase acceptance.

[19] See Chapter 7.3.1 for an examination of the role of the media in the UK in providing often incomplete and far from objective coverage of the issues around GM crops.

However, market research after these campaigns has revealed that they were very unsuccessful as consumer acceptance in Europe is falling, not rising. The percentage of European consumer 'unacceptance' with biotechnology has risen from 38% in October 1997 to 51% in October 1998. In Germany, the level of consumer 'unacceptance' of biotechnology was reported to be over 80% (Financial Times, 18 November 1998)[21]. As a result, in October 1999 the US-based firm Monsanto embarked on a consultation campaign with UK environmental and consumers organizations such as Greenpeace, the Soil Association, Friends of the Earth and the Consumers' Association (Independent on Sunday, 3 October 1999)[22].

Recent research also indicates that while education is positively related to consumer acceptance in North America, it is negatively related to consumer acceptance in Europe. Hallman and Metcalfe (1993) report that 80% of college educated respondents and less than 60% of respondents with a high school diploma or less indicated acceptance of agricultural biotechnology in New Jersey. On the other hand, research in Europe reported that consumer acceptance was negatively related to education as acceptance was reported as lowest in Denmark, Germany and The Netherlands, which were identified as the highest education states (Almas and Nygaard, 1995).

Previous research on food consumption trends in North America and Europe has concluded that European consumption patterns lag that in North America by about 10 years (Connor, 1994). The implication here is that the divergence in consumer acceptance of GM crops is just a short- to medium-term phenomenon so that trade tensions will just disappear. However, this is not a likely conclusion with respect to GM crops for several reasons. First, the very perception of agriculture is different in the two regions (see Part III) resulting in a significant cultural clash. Second, many severe and well-publicised food safety crises in Europe have created a cultural context of distrust in the food industry and in food regulators (Spriggs and Isaac, In Press). Food safety, in general, has become a sensitive, highly politicised issue throughout Europe and credence GM crops, driven by multi-national corporations appear to be just another trend to fear. In fact, it has been argued that crises and controversy create irreversible effects implying that the regulations are on an unalterable trajectory (Joly

[20] For the promotion of GM crops in Europe see Chapter 7.2.1. European multi-national firms include: Agrevo (Germany), Astra-Zeneca (UK), Novartis (Switzerland), Rhone-Poulenc (France).
[21] See also: Financial Times (15 March 1999); and Consumers' Association (1997).

and Lemarie, 1998). Third, the politically significant environmental protection movement in Europe has made the opposition of GM crops a main theme (see Chapters 4 and 7). Fourth, and not to be over-looked, the commercialisation lead in North America creates pressures to protect domestic biotechnology firms in European Member States until they are ready to compete internationally.

2.3 Conclusions

The objective of Chapter Two has been to define what is meant by the term 'GM crops' and to introduce the general factors that have made them so controversial. Essentially, GM crops are scientifically sophisticated knowledge-based developments. Like all new technology they promise great opportunity while their credence attributes raise legitimate consumer concerns about their risks. Perhaps unlike most other technologies though, consumers have concerns beyond just economic concerns about the price. They also have concerns about the human safety and health, biodiversity and broader moral, ethical and religious concerns about modern biotechnology. The information gap hinders consumer rationality while the lack of trust and choice hinders consumer sovereignty. In this sense, it is not hard to understand why many consumers lack confidence in GM crops demanding stringent regulatory responses.

The assessment of consumer acceptance reveals three important policy issues. First, different interests groups will focus on different concerns in an attempt to influence the regulatory development and integration strategy (as will be discussed in Chapters Three and Four). Second, it appears that with respect to consumer concerns associated with GM crops it is the application, management and distribution of the technology that matter most; rather than the technology per se. Third, the regulatory framework must address a broad range of concerns about the applications of GM technology to agricultural crops while simultaneously providing information, trust and choice.

In Part I, a conceptual framework for analysing regulatory regionalism created by social regulatory barriers facing the trade of GM crops has been established. It is clear that in order to understand the complexity of social regulatory barriers and the prospects and limits for regulatory integration it is vital to understand the regulatory development process – a complex interaction domestic political economy factors.

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[22] For a further discussion of UK campaigns against GM foods see Chapter 4.3.1

PART II REGULATORY DEVELOPMENT AND INTEGRATION

To explain why the traditional trade diplomacy approach is unable to deal with regulatory regionalism, it is vital to examine the interests involved in the regulatory development process. This identifies the difficulties associated with regulatory integration and the limitations of traditional trade diplomacy.

In Chapter One, it was argued that, in general, there are two perspectives on regulatory development and integration. Building on this categorisation, it is proposed that various interests may be categorised into economic and social interests where the former hold a predominantly economic perspective on regulatory development and integration and the latter hold a predominantly social perspective on regulatory development and integration. Of course, as argued in Chapter One, these perspectives result in support for different regulatory development and integration frameworks. The rationales for why the various economic and the social interests support particular frameworks for the development and integration of GM crop regulations will be examined in greater detail in Chapters Three and Four, respectively.

In Chapter Five, it will be argued that this perhaps simplistic categorisation of interests has in fact a significant degree of power in explaining the contentious debates associated with the development and integration of GM crop regulations, and hence, the problems associated with the traditional trade diplomacy approach. It will be argued that the debates and ensuing regulatory instability are the result of a lack of agreement between the two interests on even fundamental framework principles for regulating advanced technologies. It will also be argued that a failure to establish an international regulatory framework, which could be a basis for trade diplomacy, has resulted in a fragmented collection of international rules, guidelines, recommendations and codes of practice each more or less influenced by one of the two interests. Without international leadership, two dominant regulatory frameworks have emerged; a North American and a European framework. Comparing the influence of the economic and the social interests in the development of these two dominant frameworks is the objective of Chapters Six and Seven in Part III of this study.

An important point to specify is that Part II assesses interests on a general or conceptual level in order to identify the underlying rationales for the regulatory development and integration approaches supported and to identify the roots of the contentious debates surrounding GM crops. The case study of the transatlantic

regulatory regionalism (Part III), however, explicitly discusses the activities of various interest groups in North America and the European Union that have influenced the respective regulatory trajectories.

CHAPTER THREE ECONOMIC INTERESTS

In this chapter is an assessment of the regulatory development and integration approaches supported by economic interests. This includes the agricultural biotechnology industries, complementary agents in the agricultural sector, those farmers who have adopted GM crops as well as governmental and non-governmental organisations at various levels who view the commercalisation of GM crops as a positive development. Why do these interests support GM crop technology? Generally, the economic interests argue that GM crops promise significant private and public economic opportunities and they must be viewed as a crucial component of national competitiveness. Accordingly, they support regulatory development encouraging technological progress and regulatory integration encouraging stable and predictable market access rules for international economic integration.

3.1 Regulatory Development

In this section, the economic implications of GM crops are considered at the producer, sectoral and at the national level. Essentially, GM crops promise considerable private and public economic benefits extending beyond the agriculture sector making them an important element in the industrial competitiveness of a nation. Economic interests, in pursuit of these outcomes, support a stable and predictable regulatory framework ensuring technological progress.

At the farm level, first generation production trait GM crops have, of course, been developed to address important production concerns of producers. For instance, herbicide tolerant varieties address producer concerns with weed control by replacing many synthetic chemicals with one broad spectrum, post-emergent herbicide. Producer's costs are reduced as they do not have to spray their fields as often. Bt varieties with insecticidal characteristics reduce costs by eliminating the need for particular insecticides and by eliminating the costs of applying those insecticides. Further, the economic benefits of these GM crops are enhanced by their conformity with both conventional agronomic systems and with bulk commodity distribution channels thereby eliminating the need for investment in new implements and segregation practices. Given the economic benefits, GM crops have been rapidly adopted. For instance, in the United States in 1998 20.5 million hectares of transgenic crops were planted while in 1999 28.7 millions hectares were planted, a growth rate in

adoption of 8.2%. In fact, the global growth rate of adoption was 12.1% (James, 1999).

The next generations of GM crops, output trait GM crops and Bio-engineered products, are intended to secure farm-level economic benefits because by exhibiting qualities demanded by specific end-users. In other words, they have value setting them apart from conventional agricultural commodities. Producers will receive price premiums to ensure that the valuable varieties are produced under precise agronomic regimes and segregated from non-desired varieties in the field during harvest, storage and distribution.

Beyond the farm level, the genetic modification of agricultural crops encourages the integration of agricultural production both vertically within the agricultural sector and horizontally across other sectors. Indeed, the knowledge-intensification of the crop development has created economic opportunities as it has opened up new customers for agricultural production.

Along with the private economic benefits, there are public economic benefits made possible by GM crop development. Consider first that GM crops are poised in the short- to medium-term to alleviate the demands on domestic farm support programs. As previously discussed in Chapter Two, GM crops essentially represent scientific solutions to the public policy problems of variance in agricultural crop quantity and quality. Endogenous technological innovation embedded in the seed can improve crop performance and decrease the reliance of the agricultural sector upon domestic support programs. In the long-term, GM crops are poised to become a major foundation of a nation's industrial production base as applications are found across non-food industries. In fact, GM crops must be understood as a competitiveness issue of national economic importance with significant global implications. GM crop technologies allow for the creation of *endogenous comparative advantage* (Grossman and Helpman, 1991), whereby comparative advantage is no longer based on the natural endowment of factors of production. Instead, the technologies allow countries to shape their own comparative advantage and determine their economic future. As a result, public policies have been designed to ensure an internationally competitive agricultural biotechnology capacity during the so-called *agriculturalization of industry*.

Given the potential economic benefits of GM crops it is easy to understand support among some interests for the research, development and commercialisation of

these varieties. Yet, in order to take advantage of the private and public economic opportunities of GM crops, the nation must have capacity. Capacity represents the ability of both private and public personnel to apply modern biotechnology. This requires a sophisticated national infrastructure in terms of human capital, capital equipment, and investment capital. Therefore, it is not difficult to see why domestic governments in pursuit of the enormous economic potential have supported the capacity-building of biotechnology in the agricultural sector through various public policy initiatives.

The development of GM crop capacity is a function of both time and space. With respect to time, it requires years to acquire the level of scientific human capital necessary to conduct research and development at the frontiers of agricultural biotechnology. According to Baltimore (1982), the acquisition of necessary human capital alone requires thirty years of educational development per researcher. In addition, since most of the current initiatives in agricultural biotechnology are driven by the private sector, capacity also requires a mature financial system capable of channelling investment capital towards specific agricultural biotechnology applications.

With respect to national capacity as a function of space, capacity is linked to the existence of a critical mass of research activity. As previously discussed in Chapter Two, advancements in modern biotechnology generally are applicable across more specific applications so that a critical mass of research activity focused broadly on advancements in biotechnology assists the development of capacity (Barton, 1998; Theodorakopoulou and Kalaitzadonakes, 1999). It is argued that such a research capacity must have a geographical profile (Zilberman *et al.*, 1997). Even between developed countries the private and public economic importance of GM crops creates economic competition on the frontiers of science. Similar to other high-technology sectors, agricultural biotechnology is increasingly viewed as a sector of potential competitive international advantage. The concentration of capacity may result in the formation of 'agricultural industrial complexes' in the developed countries (Shimoda, 1997; Zilberman *et al.,* 1997).

The capacity issue of agricultural biotechnology has dynamic economic scale effects. A critical mass of research activity increases the potential for the development of new GM products while learning effects decease the time required for GM product development (Barton, 1998).

An important aspect of the capacity issue in developed countries is the fact that it has been driven by the private sector. As the state has retreated from both basic and applied research into the applications of agricultural biotechnology, the void has been filled by private firms. This shift in leadership has been readily supported by governments in North America and Europe. Indeed, Table 3.1 (page 78) provides evidence as to the 'private' capacity that exists in GM crop development.

Following this economic rationale, the supply-side of the agricultural sector has undergone structural change in order to build capacity. Increasingly, it has abandoned its traditional structure where agricultural products were bulk commodities and producers were considered to be a homogenous group. Very little integration occurred as commodities moved along the supply-chain through spot market transactions. As mentioned, production trait GM crops remain largely congruent with this traditional system, which is in part responsible for their popularity.

However, output trait applications or Bio-Engineered products require a greater level of vertical integration along the supply-chain to ensure segregation. End-users contract for the production of customised GM varieties tailored to meet their specific demands. These GM varieties grown for food or non-food use (e.g. pharmaceutical or industrial chemical uses) must be segregated from other varieties to ensure value capture. That is, to ensure the production and delivery of the high-value GM varieties that end-users want. Additionally, non-food use GM crops must be segregated for safety reasons to ensure that those GM crops are kept out of the food supply because they have not been designed for food production. The agricultural supply-chain must become vertically integrated in order to facilitate the research, development, production, distribution, marketing and end-use of customised, differentiated GM agricultural products.

Recent restructuring in the Agro-chemical industries supports this and is indicative of the economic need for vertical integration (see Table 3.1 for some examples). Much economic analysis has focused on the causes of vertical integration, where the key cause is the knowledge-intensification of the crop development process. In fact, the knowledge-intensification of the GM seed industry creates a practical need to ensure segregation for value capture and a commercial need to protect advanced knowledge has created powerful economic incentives for firms in the agricultural Life Sciences sector to engage in significant vertical and horizontal integration. The result

of this integration is the 'industrialization of agriculture' or the 'agriculturalization' of the national economy (Barton, 1998; Zilberman *et al.*, 1997; Shimoda, 1997).

Knowledge, embedded in the GM seed, has become the future of agricultural production as GM varieties will break the dependence of intensive agricultural production on chemicals. Realising this, Agro-chemical firms have moved upstream to acquire the seed and biotechnology firms and, hence, to own the knowledge. In the short-run, production-improved herbicide tolerant GM varieties have been developed as part of an integrated seed-chemical regime, supported by the Agro-chemical firms[1]. This shifts the chemical use from many different chemicals to one non-selective, broad spectrum herbicide.

Monsanto	• 1997 acquires Calgene (bio and seed) • 1997 acquires Agracetus (bio) • 1997 acquires Asgrow Agronomics (seed) • 1998 (May) strategic relationship in DelKab Genetics (bio and seed) • 1998 (May) ownership position in Delta and Pine Land (seed); cancelled in January 2000 by Monsanto • 1998 (May) Joint venture with Cargill for food processing and packaging • 1998 acquires Holden's Foundation Seeds (seed) $1.1 B • 1999 merger with Pharmacia & UpJohn where Agricultural Biotechnology division would be made into a separate legal entity apart from the Pharmaceutical operations.
Dow Elanco	• 1997 acquires majority in Mycogen (bio and seed)
Hoechst	• 1997 In agribusiness venture with Agrevo and Schering acquires majority in Plant Genetic Systems (PGS) (bio) $730 m • Proposed Merger with Rhone-Poulenc 'Aventis' where agricultural biotechnology (Aventis Agriculture) is separated from pharmaceutical biotechnology (Aventis Pharma)
DuPont	• 1997 strategic partnership with Pioneer Hi-Bred 20% stake • establish 'Optimum Quality Grains' • 1999 (March) acquires remaining stake in PHB $7.7 B
Novartis	• merger of Sandoz (pharma), Ciba-Geigy, Ciba seeds, Northrup-King Seeds • 1999 merger with Astra-Zeneca 'Syngenta AG' to take over the combined agricultural biotechnology
Astra-Zeneca	• 1999 merger of Astra (phama), Zeneca 53 B GBPs • 1999 merger with Novartis 'Syngenta AG' to take over the combined agricultural biotechnology

Table 3.1 Examples of Integration in the Agricultural Sector

But this is a short-run situation. The long-run is better characterised as chemical free production, due to the endogenous innovation within the seed. For

[1] For instance, Monsanto's Round up Ready Herbicide Tolerant GM varieties (cotton, corn, soybean and canola/rapeseed) and Agrevo's Liberty Link Herbicide Tolerant GM varieties (e.g. canola/rapeseed, corn, soybean).

instance, GM crops with Bt properties don't just shift chemical use, they actually decrease overall chemical use. Consequently, the Agro-chemical firms have moved upstream to buy into the knowledge base of the future, rather than remain dependent on chemicals; an ever decreasing share of production inputs.

Economists argue that this upstream movement is both predictable and consistent with economic theory (Kalaitzandonakes and Hayenga, 1999). The Agro-chemical firms seek to identify, patent and protect the industrial base of their future – knowledge of plant genomics (Joly and Lemarie, 1998). But this is no different than the multi-national pharmaceutical giants, which have long been accepted and tolerated. Agricultural 'Life Sciences' firms also face significant research and development costs for GM crops and capacity is made more efficient through economies of scale. Two economic studies have concluded that vertical integration is driven by an economically rational and efficient response to the need to identify, patent and protect the knowledge-intensification of the seed industry (Rausser *et al.*, 1999; Graff *et al.*, 1999). This conclusion, combined with the conclusion that Agro-chemical firms have moved upstream because of the limited future of their chemicals, challenges the popular argument among many critics of GM crops (see Chapter 4) that Life Sciences firms are monopolists in pursuit of anti-competitive market power in order to increase the dependence of agricultural production on chemicals. On the contrary, vertical integration is driven by both the knowledge-intensification of the seed industry and the subsequent need to build capacity and secure a competitive position in the agricultural sector by increasing a stake in biotechnology and decreasing the reliance on synthetic chemicals.

The firms developing GM crops face two important issues associated with the knowledge-intensification of agricultural crops. First, is how to be compensated for the knowledge embedded in the seed. One approach is the legal approach. Seed purchases have shifted from traditional spot transactions for conventional seeds to complicated technology use agreements (TUAs) for GM seeds, associated with a premium 'technology fee'. In 1999, Monsanto charged a technology fee of $US 6.50/bag of Round up Ready Soybean seeds, which represented a 40% premium on the GM seeds over non-GM seeds. Further, TUAs for Monsanto's herbicide tolerant soybeans prohibit both the resale of the seeds by the producer (prior to planting) and the practice of seed-saving (using harvested seeds for the next crop). While the

technology fee compensates the GM seed developer at the time of purchase, the TUAs attempt to ensure that the developer is compensated for the next crop as well.

An alternative approach for ensuring compensation for the commercial use of the knowledge embedded in the seed is the biotechnological approach through the use of so-called 'terminator' or 'traitor' technology[2]. The objective is to develop GM seeds that are sterile and cannot be used for a second planting or cannot cross-pollinate with other plants. Simply, this approach bypasses the need for legal TUAs. This is actually not a new approach as F1 hybrid varieties of corn seeds used for decades are sterile after harvest and cannot be successfully planted the following crop season.

The second important issue for GM crop developers, associated with the knowledge intensification of the seed industry, is how to protect their knowledge from other firms. A common approach to vertical integration has been through acquisition and consolidation (see Table 3.1), rather than other tools of industrial organisation such as licensing agreements or contractual arrangements for technology use between biotechnology, seed and agro-chemical firms. It has been argued that acquisition and consolidation have been the chosen strategy, again not for anti-competitive monopoly reasons, but because of the current regime for intellectual property protection (Rausser *et al.*, 1999). Essentially, outright ownership of the knowledge is the sure way to protect it. If intellectual property protection laws were stronger and internationally respected then technology licensing would be the chosen strategy and not direct ownership. The economic rationale behind intellectual property rights (IPRs), such as patents and plant-breeders rights (PBRs), is that they provide an incentive for both investment in inventive activities and for technology transfer (Malchup, 1958). Zilberman (1999) argued that a weak IPR regime over GM crop technologies has encouraged too much agro-industrial concentration because only direct ownership will ensure that intellectual property is protected.

The horizontal integration of agricultural production simply represents an inter-industry extension of the issues associated with the vertical integration of the agricultural sector. Horizontal integration is motivated by the output trait applications

[2] Terminator technology is patented by the USDA and Delta and Pine Land, now owned by Monsanto, while traitor technology is being developed by UK-based Astra-Zeneca. However, this technology is not in use.

and Bio-Engineered products allowing GM crops to meet the demands of new end-users, such as pharmaceutical, nutriceutical or industrial firms.

Given the fundamental role of capacity in the research, development and commercialisation of GM crops, the significant public and private investment in capital that must be made in order to build capacity and the necessary restructuring of the agricultural sector, economic interests naturally support a stable regulatory framework that encourages technological progress through a scientific rationality approach to Risk Analysis and that clarifies intellectual property rights. This is not to suggest that economic interests ignore safety issues. On the contrary, economic interests generally provide significant scope for safety issues in regulatory frameworks. They often insist, however, that there is a sound scientific basis for determining safety, subject to an objective, rules-based analysis of risk so that stability and commercial predictability are built into the framework.

3.2 Regulatory Integration: The Traditional Trade Approach

The objective of this section is to examine the type of regulatory integration supported by economic interests and to examine how the international economic integration approach has led to the current international trade regime characterised by the World Trade Organization (WTO), its agreements and its affiliated international institutions.

Given the central role that technological progress plays in the economic perspective, economic interests tend to support regulatory integration strategies that ensure international market access for advanced technology products. For instance, market access for GM crops is an important issue because they require significant research and development investment and, as a result, are often commercialised at the international level in order to maximise market share and recover the substantial R&D costs in short-lived markets for knowledge-based products.

The economic perspective of international economic integration and regulatory competition has dominated the traditional trade diplomacy approach to regulatory integration. This approach is characterised as closed-door, non-transparent market access negotiations resulting in political compromises and concessions between sovereign states. The negotiations are aimed at establishing trade agreements outlining certain and predictable rules for the market access of traded products. They have been built on the premise that industrial interests lobby domestic governments to provide

commercial protectionism from foreign imports or support for domestic exporters. Trade agreements attempt to limit the ability of governments to acquiesce to this pressure in order to enhance international economic integration (Perdikis *et al.*, 1999).

Further, the traditional trade approach attempts to disentangle trade barriers erected because of safety reasons, from those erected for non-safety reasons. The former are subject to a scientific justification for the safety measure. In the event of a justification, it is legitimate for a country to impose a unilateral safety barrier to particular imported products. The latter, non-safety measures, are subject to the traditional trade principles of non-discrimination. In the event that a country imposes a trade barrier against a certain product, this barrier must be equally enforced across all like products both domestic and foreign.

Social regulatory barriers facing GM crops have emerged as a contentious issue facing the international trading regime[3]. For instance, at the 1999 Ministerial Meeting of the World Trade Organization (WTO) in Seattle, Canada and the US jointly proposed a World Trade Biotechnology Initiative under the auspices of the WTO. There were two objectives. First, to establish an international fact-finding group to examine the trade issues raised by the development and commercialisation of GM crops and second, to establish binding international trade rules for GM crops. While the EU accepted the first objective, it completely rejected the second objective, stating:

> *We reject requests to deal with biotechnology exclusively on trade grounds. We reject market access negotiations for GMOs. We reject any attempt to undermine the EU right to regulate. And we reject any attempt to derail, divert or delay the biosafety talks.*

This statement clearly illustrates the trade controversy associated with GM crops and social regulatory barriers. Basically, the controversy arises because some countries are in pursuit of an international economic integration approach to GM crop regulations (i.e. Canada and the US) which is largely the approach of traditional trade diplomacy while other countries are in pursuit of an international social integration approach to GM crops, as evidenced by the EU support for the Biosafety Protocol (see Chapter 4.2). Moreover, due to the European Union's rejection of the World Trade

[3] For a history of the trading regime see Grimwade (1996) and Jovanovic (1998e).

Biotechnology Initiative, there is no co-ordinated WTO initiative for addressing trade issues associated with GM crops.

The question may be raised: what is it about the traditional trade diplomacy approach that the EU rejects? To understand the traditional trade approach to regulatory integration supported by economic interests it is necessary to examine the traditional approach to social regulatory issues such as food safety and environmental protection. Essentially, the objective is to identify what are the 'trade grounds' that the EU has rejected for assessing social regulatory barriers.

There is common ground between food safety and environmental protection social regulations. First, both are traditionally domestic areas that have qualified for exemptions under international trade agreements and their relationship with the rights and obligations of trade agreements remains controversial and uncertain. Second, domestic standards and regulations to ensure food safety and environmental protection employ precaution in the face of uncertainty when scientific evidence is insufficient; the so-called precautionary principle. Third, the demand for food safety and environmental protection measures is generally social protectionism emerging from non-industrial actors, such as consumer and environmental organisations. Fourth, the demand for both food safety and environmental protection measures is income elastic, that is, countries with higher incomes have higher standards for food safety and environmental protection. In short, both food safety and environmental protection measures can be social regulatory barriers. In fact, it is difficult to disentangle GM crop regulations to ensure food safety from those designed to ensure environmental protection.

The principle trade concern with food safety and environmental-type social regulatory barriers is that, while they incur market access delay and prohibition, there are uncertain trade rules outlining their legitimate use. Currently under the WTO, there is greater discipline on food safety-type social regulatory barriers than those for environmental protection while there are no disciplines for the use of social normative regulations addressing moral, ethical or religious concerns with traded products. Yet, these food safety rules have been controversial and, in the case of hormone-treated beef, have created a significant transatlantic trade diplomacy challenge. Indeed, it is worth considering the threat that as the WTO reinforces its rules for food safety, anti-GM crop pressures will increasingly shift from food safety to environmental protection and social norm justifications for social regulatory barriers – regulations

that are less rules-based and less-science based, making them more difficult to integrate.

3.2.1 Food Safety and Trade

Both the international trade of agricultural products and the domestic regulation of food have a long history. Trade objectives of market liberalisation and the removal of market fragmentation have not always been congruent with domestic regulations designed to ensure the safety, wholesomeness and adequate labelling of food products. The purpose of this section is to examine how food safety issues are dealt with according to the traditional trade diplomacy approach of the WTO.

It is important to note that it is difficult to separate food safety issues from those associated with food quality. Some have argued that safety is only one of several attributes that together contribute to the quality of a food product (Caswell and Hooker, 1995). Therefore, although this section is focused on food safety, a discussion of food quality will at times be necessary.

In general, food safety issues are dealt with at the WTO under the Agreement on Sanitary and Phyto-sanitary Measures (SPS Agreement) while non-safety food quality issues are dealt with at the WTO under the Agreement on Technical Barriers to Trade (TBT). Both agreements defer to standards developed in international organisations. For instance, the SPS Agreement defers to the international measures on food safety and quality established under the Codex Alimentarius and the International Plant Protection Convention, two international institutions which will also be examined in their trade context. In fact, the International Plant Protection Convention provides an illustrative example of not only food safety measures established at the international level, but also of the difficulty with disentangling food safety measures from environmental protection measures.

A. The Agreement on Sanitary and Phyto-Sanitary Measures

The SPS Agreement was the product of a convergence of economic interests such as food exporting countries and multinational food processing and distributing companies who shared a common concern about market access barriers facing food trade. They believed that previous trade agreements simple did not provide enough discipline in order to protect their international economic integration interests. In short, the SPS Agreement seeks to discipline the use of food safety measures in order

to establish predictable and stable market access rules promoting international economic integration.

By way of background, the original General Agreement on Tariffs and Trade (GATT 1948) was built on the principle of non-discrimination, summarised by the following three provisions:

1. the national treatment provisions (Article I) which states that foreign products must be treated like domestic products;
2. the most-favoured nation principle (Article III) which states there should be no discrimination between products originating from different countries; and
3. a distinction between processes and products whereby all 'like products' were to be treated the same regardless of the process used in their production.

These principles essentially mean that 'like' or 'substantially equivalent' products must be subject to the same regulations in a particular regulatory jurisdiction regardless of their origin or the production and processing methods (PPMs) used in their production.

The GATT 1948 was, however, ambiguous on the issue of trade rules and domestic food safety measures as countries held significant discretion to establish their own food safety and food quality regulations. For example, a number of the GATT articles specifically permitted regulations setting out national "standards or regulations for the classification, grading or marketing of commodities in international trade" (Art. XI) and the adoption or enforcement of measures necessary to protect human, animal or plant life or health (Art. XX(b)). In an attempt to be consistent with non-discrimination, the discretionary measures under Articles XI and XX(b) could not be applied in such a manner as to cause arbitrary or unjustifiable discrimination between countries or disguised restrictions on trade.

The SPS Agreement, driven by economic interests, attempted to deal with the contentious ambiguities associated with discretionary food safety standards by specifically outlining permissible trade restricting measures that WTO Members may enact in order to protect human, animal and plant safety and health from the import of agricultural products. In this sense, it represents an economic approach to disentangling legitimate social regulatory barriers from illegitimate ones.

Accordingly, the objective of the SPS Agreement is to outline rules for when and how Members can deny market access to particular exporters because of the risk that imports will contain pests or diseases. Unsafe imports can jeopardise human

safety and health either directly by making imported foodstuffs unsafe, or indirectly by infecting domestic food inputs including livestock and agricultural plants that are part of the domestic food chain. There is a crucial distinction to note. The SPS Agreement targets measures taken to protect the domestic food supply, not measures taken to target overall domestic biodiversity. In this sense, the SPS Agreement relates to food safety measures, not environmental protection measures, although in practice this distinction is blurred.

The SPS Agreement states that "no member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health"[4] which remains in accordance with the traditional exemption provisions under Article XX(b) GATT 1994. In the SPS Agreement, the risks that measures may target are those arising from:

- *"the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;*
- *additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs;*
- *diseases carried by animals, plants or products thereof."(SPS Agreement, Annex A).*

To prevent imported products from jeopardising the safety of the domestic food supply, Members may restrict or prevent imports through the use of mandatory sanitary and phyto-sanitary measures. There are four important provisions of the SPS Agreement, which differ from traditional trade principles, and support the unilateral establishment of SPS measures by Members.

First, under the SPS Agreement, Members may discriminate against imports because of the presence of the above risks in the exporting country (SPS Agreement, Article 2:3). The agreement recognises that different regions with different geographical conditions and agronomic practices face different incidence of pests and disease. As a result, it is not possible to establish uniform SPS measures to apply to all exporters according to the principles of non-discrimination. Instead, trade measures need to specifically target those imports that may contaminate the domestic food supply, while other imported agricultural products may not face the same measures. This provision is an important exemption to the traditional non-discrimination

principles. Members are not required to grant either national treatment or most-favoured nation status to agricultural exporters whose products risk contaminating the domestic food supply.

Second, according to the agreement, Members may also establish domestic SPS measures higher than the accepted international standard if there is scientific justification to do so (SPS Agreement, Article 3:3). Generally, international trade agreements commit Members to adopt international standards if available, however, the SPS Agreement permits Members to establish even higher standards.

Third, the SPS Agreement permits Members to establish SPS measures based on scientific risk as well as broader assessments of risk such as relevant economic factors that include:

- *the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of the disease or pest;*
- *the costs of control or eradication in the territory of the importing Member;*
- *the relative cost-effectiveness of alternative approaches to limiting risks (SPS Agreement, Article 5:3)*

Trade agreements traditionally avoid such socio-economic assessments because of the subjectivity complications that are associated with them. Indeed, as previously discussed, the economic perspective attempts to de-politicise trade and make it a function of comparative advantage (WTO, 1995), yet the SPS Agreement recognises the socio-economic nature of food safety regulations and permits such consideration.

Fourth, and finally, under the SPS Agreement, Members may establish provisional SPS measures based on precaution, in the event that there is insufficient scientific evidence to conduct an appropriate risk assessment. The Agreement states:

> *In cases where the relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phyto-sanitary measures on the basis of available pertinent information, including that from sanitary or phyto-sanitary measures applied by other Members. In such circumstances, Members shall seek to obtain additional information necessary for a more objective assessment of risk and review the sanitary or phyto-sanitary*

[4] Agreement on the Application of Sanitary and Phyto-Sanitary Measures, Uruguay Round of

measure accordingly within a reasonable amount of time. (SPS Agreement, Article 5:7).

That is, Members are permitted to establish trade barriers based on the precautionary principle. These barriers can remain in place until enough scientific evidence about the risk has been compiled. Indeed, the temporary barrier provision of the Agreement is a unique provision in terms of international trade agreements.

While the SPS Agreement allows Members considerable scope to impose unilateral social regulatory barriers, there are important conditions on the sanitary and phyto-sanitary measures that Members may unilaterally take in order to prevent them from being used as disguised protectionist barriers. It will be argued that these conditions reflect the predominant influence of the scientific rationality perspective on regulatory development and regulatory integration that is supported by economic interests.

To facilitate international trade, Members are committed to both the international harmonisation of SPS measures and to the mutual recognition of measures employed by other Members. With respect to harmonisation, Members commit to adopting international standards, guidelines or recommendations as the prevailing national standards in order to promote international harmonisation (SPS Agreement, Preamble). For food safety, the relevant international institution is the Codex Alimentarius Commission (CAC), for animal safety the International Office of Epizootics (OIE) and for plant safety the International Plant Protection Convention (IPPC). With respect to mutual recognition, Members are committed, in principle, to granting equivalence to the SPS measures adopted by exporting countries "if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phyto-sanitary protection." (SPS Agreement, Article 4:1). To facilitate the process, the importing Member must be allowed to conduct a conformance assessment including inspection, testing, monitoring and evaluation of the measures in place in the exporting Member.

Yet, as mentioned, Members are permitted to exceed international standards provided there is a scientific justification to do so. Hence, an important condition is a scientific justification. According to the Agreement, unilateral SPS measures must be

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Multilateral Trade Negotiations Legal Texts, pp. 69-84 (the "SPS Agreement"), Preamble

"based on scientific principles" and cannot be maintained "without sufficient scientific evidence" unless it is a temporary, precautionary measure (SPS Agreement, Article 2:2). The science-based measures adopted must be proportional to the risk that is being targeted. In order to assess the risks, Members are committed to considering the risk assessment techniques used in the international standard setting institutions, even if the relevant international standard is not being used (SPS Agreement, Article 5:1). Further, the Agreement states that:

> *In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions and quarantine and other treatment (SPS Agreement, Article 5:2).*

Hence, the SPS Agreement requires Members to provide a scientific justification for the adoption of measures where the scientific justification is crucial in supporting the domestic measure in the event of a trade challenge.

> *When a Member has reason to believe that a specific sanitary or phyto-sanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phyto-sanitary measure may be requested and shall be provided by the Member maintaining the measure (SPS Agreement, Article 5:8).*

According to the Agreement, in the event of a trade dispute over the use of a food safety measure, the WTO Dispute Settlement Panel seeks the scientific advice of the Codex Alimentarius Commission (CAC). Without an acceptable scientific justification, it is unlikely that a trade dispute decision by the members of a WTO dispute settlement panel or an appellate body will support the unilateral SPS measure. In this sense, even if Members do not adopt international standards, it is important that domestic food safety measures remain congruent with the international Risk Analysis

approach of the CAC in the event of a trade dispute. The CAC will be discussed in more detail in sub-section C, below.

The SPS Agreement also commits Members to publish a draft of the domestic measures to the SPS Committee and to allow for a 60-day review and comment period for all concerned exporters (SPS Agreement, Annex B:5). The logic is that such a review and consultation process may proactively avoid future trade disputes by ensuring that the food safety measures adopted by a Member take into account the process and production realities in exporting countries. The Agreement obliges, although does not require, the importing Member to take full account of the comments and endeavour to ensure that the SPS measure fulfils a legitimate and scientifically justifiable safety objective without unduly affecting agricultural trade.

The Marrakech Agreement 1994 included a provision for the SPS Committee to conduct a review of the Agreement in order to examine its progress in enhancing trade liberalisation and to identify points of clarification that may be addressed through amendments. The general interpretation of the 1998 review was that nothing could be amended without creating significant controversy and/or requiring an opening up of the Agreement. Essentially, the SPS Agreement has been established congruent with a scientific rationality approach to economic integration and decision-making has favoured economic trade interests. Dealing with concerns would require an opening up of the Agreement to allow for greater influence from the social rationality perspective. As a result, the Agreement was virtually left unchanged.

Clearly, the SPS agreement outlines a scientific rationality approach to regulatory development supported by economic interests. It aims to establish predictable and certain rules for legitimate social regulations according to a sound scientific basis. It represents a 'safe harbour' for Members since it allows them to take unilateral trade restriction measures against agricultural imports to address domestic concerns about food safety in the face of risk and uncertainty. However, there are important conditions on the unilateral use of SPS measures in order to prevent unnecessary trade distortions. The challenge is finding the line between SPS measures that legitimately restrict trade in order to protect human, animal and plant safety or health and those SPS measures that unnecessarily restrict trade. According to the Agreement, the most objective way to define the line is through a scientific risk assessment procedure according to the Risk Analysis framework supported by the CAC. An SPS measure used by a Member will be considered legitimate if there is

sufficient scientific proof for its use and if it is the measure with the lowest cost to the consumer and the international trading system (Roberts *et al.*, 1998).

Indeed, this approach should come as no surprise as the SPS Agreement came about because it was in the economic interests of large, multinational agri-food companies and the economic interests of export-oriented countries. During the Uruguay Round negotiations these interests held significant policy power, even in the EU. Phillips (1991) argued that the EU approached the negotiations from the economic perspective and with an export-orientation. A broad coalition of interests including farmers and consumers viewed the SPS Agreement as a potential win-win situation whereby market access rules could be clarified, yet social food safety regulations would be protected. Hence, the EU was in support of the Agreement's international trade rules for food safety-type social regulatory barriers.

With respect to the use of biotechnology in food production, the SPS Committee has deferred to the work of the CAC in establishing both legitimate scientific risk analysis procedures and regulatory guidelines based on those procedures. Hence, it is crucial to examine the CAC.

In summary, it is important to note at this point that according to the SPS Agreement food safety-type social regulatory barriers to GM crops will be assessed in terms of their scientific justification and their trade impact. In practice, this means that there is no scope under the WTO to impose legitimate trade barriers predicated on social preferences beyond a scientifically justified prevention of risk. In addition, social regulatory barriers that are justified must also meet the requirement of minimum trade disruption. In other words, trade and market access imperatives dominate even justified social regulatory barriers according to the economic integration approach of the SPS Agreement.

B. The Agreement on Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (TBT) deals with the technical, non-safety food quality issues such as nutrition, analysis, grading, labelling, packaging, symbols, markings, terminology and protection against deceptive or fraudulent practices. The TBT Agreement also has provisions on establishing conformity assessments between trading partners. Conformity assessments, which are important for mutual recognition efforts, are any procedures used, either directly or indirectly, to determine that relevant requirements in technical regulations (mandatory

requirements) and standards (voluntary requirements) are fulfilled which includes: sampling; testing and inspection; evaluation, verification and assurance; registration, accreditation and approval. Further, the TBT Agreement deals with broader issues of food trade not easily captured in a science-based framework of Risk Analysis. Therefore, the role of the TBT Agreement in food trade is important and needs to be assessed.[5]

Historically, concern about the potential impact of technical standards and product labelling upon international agricultural trade has been voiced at the multilateral level since the mid 1970s driven mainly by economic interests in Australia, Canada and the US. The primary concern was that technical food standards, including labelling schemes, might be used to either restrict market access or to confer an advantage to domestic products in the domestic marketplace. Yet, such standards could be used in a discretionary manner with no real discipline on their application.

The Tokyo Round of the GATT introduced international trade discipline of food quality regulations, including labelling measures, through the Technical Barriers to Trade (TBT) Code. The essence of the TBT Code was to establish international obligations on technical regulations, standards and conformance assessments for both transparency and notification based on the trade principle of non-discrimination (OECD, 1995b; Caldwell, 1998).

Yet, despite this code, agricultural exporters still had concerns with food quality measures because food safety measures were generally still exempt from any discipline. They wanted to see the TBT Code which only applied to a limited number of developed contracting parties, strengthened and extended to cover all WTO members. As a result, negotiations in the Uruguay Round produced the TBT Agreement.

There are three similarities between the SPS and the TBT Agreements. First, the TBT Agreement allows Members to establish trade-restricting measures in order to protect human and environmental health and safety and to ensure the quality of imported products, the so-called 'legitimate objectives', provided that the measures do not unnecessarily obstruct international trade (TBT Agreement, Article 2:2). That is,

[5] The TBT Agreement also has relevance to environmental protection issues associated with agricultural biotechnology, to be discussed in Section 3.2.2 A. The relevance of the TBT Agreement to environmental protection lies with its jurisdiction over process and production methods (PPMs).

similar to the SPS Agreement, the social regulations of Members may be trade barriers to imported products.

Second, it requires Members to base their national standards on international measures established by international standards setting bodies (TBT Agreement, Article 2:4). When internationally agreed standards cannot be adopted due to geographical, climatic or technological reasons, the Member must publish the draft measures in order to allow potentially affected foreign producers an opportunity to respond to them (TBT Agreement, Article 2:9). It is anticipated that concerns of exporters will then be incorporated into any subsequent measures.

Third, the TBT Agreement requires that, where applicable, national measures should be scientifically justifiable (TBT Agreement, Article 2:2). The Agreement includes specified criteria that Members must account for in formulating TBT measures in order to ensure that measures do not create unnecessary regulatory barriers to trade. Similar to the SPS Agreement, the TBT Agreement employs a scientific rationality approach in order to identify legitimate social regulatory barriers.

Despite the similarities, there are four differences between the SPS and the TBT Agreements. First, unlike the SPS Agreement, which permits discrimination in the application of trade-restricting measures, the TBT Agreement is based on the traditional trade principles of non-discrimination. The Agreement states that measures should be applied on a most-favoured nation (MFN) basis to all imported products from all contracting parties (TBT Agreement, Article 2:1 – MFN Principle of Non-Discrimination). It also states that measures should not extend to imported products treatment that is less favourable than that extended to domestically produced 'like' products (TBT Agreement, Article 2:1 – National Treatment Principle).

Second, whereas the SPS Agreement deals with mandatory national food safety measures, the TBT Agreement deals with both mandatory (technical requirements) and voluntary (standards) measures. Both mandatory and voluntary measures can address product characteristics, process and production methods (PPMs), terminology and symbols and packaging and labelling requirements (i.e. prevention of deceptive advertising practices). Voluntary standards are subject to the TBT Code of Good Practice for the Preparation, Adoption and Application of Standards which urges Members to use their best endeavours to ensure that voluntary trade-restricting measures are subject to the same principles and rules as mandatory standards (TBT Agreement, Article 4 & Annex 3). The Code urges Members to use

international standards as a basis for national voluntary standards and to participate fully in the preparation of international standards.

Third, unlike the SPS Agreement, the TBT Agreement does not allow for provisional trade restriction based on precaution where scientific evidence is insufficient.

Fourth, although the TBT Agreement requires that measures should be scientifically justifiable, the problems with determining appropriate scientific risk assessment procedures for non-safety issues and other legitimate objectives, such as labelling for the consumers' right to know, are enormous. As a result, the scientific justification principle under the TBT Agreement is considerably weaker than under the SPS Agreement. For instance, under the TBT Agreement labelling standards can prevent deceptive marketing practices that adversely impact informed consumerism. In such circumstances, domestic measures do not need a science-basis for justification. There does appear to be greater scope under the TBT Agreement to permit food quality-type social regulatory barriers. Specifically, with respect to GM crops, the TBT Agreement's mandatory and voluntary labelling provisions are most relevant.

The WTO's Committee on Technical Barriers to Trade provides a forum for Members to raise concerns about the labelling legislation of other Members and how this legislation might contravene the rights and obligations under the agreement. A recent example, is a US submission to the TBT Committee underlying concerns with the EU labelling regulation 1139/98 (the GM Soya/Maize Regulation) (WTO 1998). The US submission indicated that the US felt bilateral consultations with the EU on the proposed regulation did not address fundamental US concerns, supported by Brazil, Canada and New Zealand. The submission states that "the United States urgently requests that the EC address our concerns and comply with its obligations under the Agreement, with respect to these and future regulations." Essentially, the US position is that Regulation 1139/98 cannot achieve its alleged 'legitimate objective' and that the implementation rules make compliance by producers from other Members overly difficult; concluding that it is an unjustified barrier to trade. Therefore, the TBT Agreement can become an important forum for dealing with the social regulatory barriers to GM crops. Labelling under the WTO is discussed more fully in Chapter 5.

C. The Codex Alimentarius

Economic interests support the work of the Codex in establishing international food safety and food quality measures because the Codex approach has always been congruent with the scientific rationality approach to regulatory development. And, due to its focus on scientific rationality, economic interests supported the linking of Codex with international trade agreements. For instance, the formal linking of trade rules and Codex food standards was examined in 1991 at the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade held in co-operation with the GATT Secretariat. The motivation for this conference was that the draft SPS Agreement cited the Codex Alimentarius as the international institution responsible for developing harmonised food standards. Essentially, the objective of this conference was to make the Codex procedures more trade congruent (this conference will be discussed in greater detail below).

In order to establish the science-basis sufficient to justify the use of SPS and TBT – related measures, both the SPS and TBT Agreements defer to the international food safety and quality measures established under the Codex Alimentarius. The SPS Agreement states "Members shall base their sanitary or phyto-sanitary measures on international standards, guidelines or recommendations" (SPS Agreement, Article 3:1). The TBT Agreement states that "(w)ith a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part...in the preparation by appropriate international standardizing bodies of international standards for products for which they have either adopted, or expect to adopt, technical regulations" (TBT Agreement, Article 2:6). In other words, Codex food safety standards are relevant to the SPS Agreement while Codex food quality standards are relevant for the TBT Agreement.

Because of its focus on scientific rationality and its links with international trade agreements, the Codex is very vulnerable to criticisms from those who support a social rationality regulatory approach and who reject the traditional trade approach of international economic integration only. This is precisely the conflict that emerges with respect to GM crops. To better understand this conflict, the discussion begins with an examination of the scientific rationality approach of the Codex followed by a discussion of the current debates on GM crops and GM foods at the Codex.

The Codex Alimentarius, created in the early 1960s under the United Nations' (UN) Food Standards Programme, is a joint agency of the UN's Food and Agriculture

Organisation (FAO) and the World Health Organisation (WHO). The FAO, established in 1945, has responsibilities covering food nutrition and international food standards while the WHO, established in 1948, has responsibilities covering human health and food standards. The first meeting of the Joint FAO/WHO Expert Committee on Nutrition in 1950 concluded that there was a need for the international harmonisation of food standards based on science. The meeting report explained that:

> *(f)ood regulations in different countries are often conflicting or contradictory. Legislation governing preservation, nomenclature and acceptable food standards often varies widely from country to country. New legislation not based on scientific knowledge is often introduced, and little account may be taken of nutritional principles in formulating regulations.(FAO/WHO 1950).*

In this sense, the initial motivation for a Codex Alimentarius was to establish science-based, international standards for food safety and quality in order to enhance consumer protection and reduce market fragmentation. In this sense, it is not difficult to appreciate why the Codex enjoys significant support from economic interests.

In 1960, the FAO Regional Conference for Europe endorsed the idea of creating an international food code governed jointly by the FAO and WHO and based on the Codex Alimentarius Europeaus. In 1961, the Eleventh Session of the Conference of the FAO established the Statutes and Rules of Procedures of the Codex Alimentarius Commission (CAC). Also, it was proposed that the start-up costs of the CAC be supported by a trust fund in which both national governments and industry groups made voluntary contributions (Frawley, 1987). In 1962, the Joint FAO/WHO Food Standards Conference requested that the CAC implement a joint FAO/WHO food standards programme and to create the Codex Alimentarius. Finally, in 1963 at the Sixteenth World Health Assembly of the WHO the establishment of the Joint FAO/WHO Programme on Food Standards was approved.

The creation of the Codex Alimentarius was driven largely by desires to ensure food safety and consumer protection in the context of rapidly growing international food trade. Widely different interests shared the demand for greater international co-operation and international leadership in food standards. For instance, on one hand, international trade associations were frustrated by the market fragmentation of divergent regulations and, hence, supported international co-ordination efforts. While on the other hand, consumers' concerns, including the food reform movements of the

late 1940s and early 1950s were concerned with the lack of international co-ordination of food safety regulations as the international trade of food products increased. It has been argued that:

> *(t)he Codex Alimentarius was a response to a widely recognised need. It did not just happen. It was a product of a long evolutionary process involving a wide cross-section of the global community. Many people representing many interests and disciplines were involved in the process...(Frawley, 1987).*

Therefore, the Codex emerged from a common desire for internationally co-ordinated food safety and quality rules.

Administratively, there are three separate Codex agencies which together work to develop the Codex Alimentarius; the Codex Alimentarius Commission (CAC), the Codex Secretariat and the Codex Executive Committee. The first, and already mentioned, is the Codex Alimentarius Commission (CAC) which meets every two years. To date, there have been 23 Sessions of the CAC. Commission membership is on a country basis where all member countries to the United Nations may be CAC members. Currently, the Commission has 165 member countries representing over 97% of the world's population who participate, in varying degrees, in the development of international food standards. Member countries are represented at CAC Sessions by national delegations composed of senior officials (usually health officials) appointed by their governments and may also include industry representatives, academics and representatives of non-governmental organisations. Although the CAC Sessions were initially the domain of the developed countries, the number of developing country delegations has steadily increased to nearly three times the number of developed country delegations (Frawley, 1987). There is also scope in the CAC Sessions for international non-governmental organisations (INGOs) to participate as 'observers' in order to express their points of view, with the restriction that observers cannot participate in final decision-making, only national delegations can. National level non-governmental organisations are expected to participate through the national delegations of their home countries. Most Member countries have established a delegation contact point, for instance, in 1992 the UK established the National Codex Consultative Committee.

The CAC is governed according to Statutes and Rules of Procedures. The Statutes identify the reasons for the establishment of the Commission and the legal

basis for its activities. For instance, according to Article 1 of the Statutes of the CAC, there are five guiding principles for the work of the Commission (CAC, 1997):

a) to protect the health of consumers and to ensure fair practices in food trade;
b) to promote the international co-ordination of all food standards among international governmental and non-governmental organisations;
c) to establish priorities for food standards and to initiate and guide the development of draft standards along with appropriate organisations;
d) to finalise draft standards and to publish final food standards including final standards developed by other international organisations which have been internationally accepted and to publish these standards in the Codex Alimentarius either as a regional or a world wide standard;
e) to amend published final food standards as new evidence is collected.

The Rules of Procedure of the CAC identify the how the intergovernmental body operates. The rules include the appointment of Commission officers, the frequency and operation of the Commission, procedures on voting, the establishment of subsidiary bodies and issues concerning the Commission's budget and expenditures.

The CAC is the body responsible for establishing international measures and for co-ordinating an international dialogue on important food safety and quality issues through various expert committees and scientific consultations. According to the Rules of Procedure, the Commission can establish two kinds of subsidiary committees, Codex Committees and Co-ordinating Committees. The former, Codex Committees are made up of 15 Commodity Committees and 9 General Subject Committees (Table 3.2). Committees are chaired by a host member country and the committee may be active or dormant. Host members are very influential since they, in collaboration with the Codex Secretariat, establish the agenda of meetings and issue invitations to member delegations and observers.

Co-ordinating Committees have no host country because they are organised according to regions. There are five such committees representing Africa, Asia, Europe, Latin America and the Caribbean as well as North America and Southwest Pacific. Along with the Committees, there are joint FAO/WHO expert groups which provide advice and guidance to the Codex (Table 3.2).

The second Codex agency is the permanent Codex Secretariat which is located in Rome and administered by the FAO's Food Quality and Standards Service within

the Food and Nutrition Division. The purpose of the Secretariat is to provide day-to-day support for member countries as they attempt to interpret, develop and implement national food regulation congruent with the Codex Alimentarius. The Codex Secretary is an FAO official who serves also as the Chief of the Joint FAO/WHO Food Standards Programme.

Vertical Commodity Committees	**Country**
Cereals, pulses and legumes	United States
Vegetable proteins	Canada
Tropical fresh fruits and vegetables	Mexico
Processed fruits and vegetables	United States
Fats and oils	United Kingdom
Processed meat and meat products	Denmark
Meat hygiene	New Zealand
Fish and fishery products	Norway
Milk and milk products	New Zealand
Sugars	United Kingdom
Cocoa products and chocolate	Switzerland
Edible ices	Sweden
Soups and broths	Switzerland
Natural Mineral Waters	Switzerland
Horizontal General Subject Committees	**Country**
Residues of veterinary drugs in food	United States
Import/export inspection and certification	Australia
Food additives and contaminants	Netherlands
General principles	France
Pesticide residues	Netherlands
Food labelling	Canada
Methods of Analysis and Sampling	Hungary
Food hygiene	United States
Nutrition and Foods for Special dietary uses	Germany
Expert Committees	
Joint Expert Committee on Food Additives (JECFA) 1955	
Joint Meeting on Pesticide Residues (JMPR) 1963	
Joint Expert Committee on Fruit Juices	
Joint Expert Committee on Quick Frozen Foods	

Table 3.2 Codex Commodity and General Subject Committees and Expert Committees

The third Codex agency is the Codex Executive Committee. The Executive Committee meets yearly and, unlike the CAC, is organised according to principal regions: Europe; Africa; Asia; the South Pacific; Latin America and North America. Hence, the Codex Executive Committee provides the regional perspective on food safety, consumer protection and, increasingly, agri-food trade.

The Codex Alimentarius, is composed of standards, codes of practice, guidelines and recommendations pertaining to food safety and quality. To date, 237 Commodity food standards, 41 Codes of Hygienic or Technological Practice, 185

Pesticide Evaluations, 3,274 Maximum Residue Limits for Pesticdes, 25 Guidelines for Contaminants, 1005 Food Additive Evaluations and 54 Veterinary Drug Evaluations have been developed (CAC, 1997).

Since the Codex Alimentarius attempts to develop universal food safety and consumer protection principles based on a tradition of consensual decision-making, it should come as no surprise that the administrative process is lengthy and subject to many iterative review processes. A Codex commodity food standard is adopted only after eight stages or steps of consultation have been completed. The eight steps include (CAC, 1997):

1. A food safety issue is identified by a national government or a subsidiary committee of the CAC and presented at a CAC plenary session (every two years), where, if it is determined that a Codex food standard ought to be elaborated, the CAC or the Codex Executive Committee assigns the issue to either a commodity or a general subject committee;
2. The committee presents its elaboration, based on Codex food standard elements, to the Codex Secretariat who produces a Proposed Draft Standard;
3. The Proposed Draft Standard is sent to all member governments and identified international non-governmental organisations (INGOs) for review and comments;
4. Comments from step 3 are returned to the Committee who initially elaborated the food standard;
5. The committee amends the Proposed Draft Standard subject to the review comments and the amended Draft Standard is presented to the CAC by the Secretariat at a plenary session where it may be adopted as a Draft Standard;
6. The adopted Draft Standard is sent to all member governments and identified INGOs for further comment;
7. Comments are returned to the Committee through the Secretariat for amendments to the Draft Standard;
8. The amended Draft Standard is presented to the CAC for adoption as a Codex Standard to be sent to member governments for acceptance.

Along with Codex commodity food standards, the Codex Alimentarius also includes Codex General Standards, developed by the horizontal General Subject Committees, which apply to all foods.

A final Codex standard includes several elements. First, it includes a description of the product and the essential composition and quality factors which identify the product from close substitutes. Second, the standard includes both identification and analysis of any additives and potential contaminants in the food product. Third, the food standard incorporates established Codex requirements such as the Codex product hygiene requirements and the Codex labelling requirements. Fourth, the standard includes a complete description of the scientific procedures used to sample and analyse the product during review. Fifth, the standard specifies any labelling requirements in accordance with the Codex General Standard for the Labelling of Pre-packaged Foods.

Determination of the safety of the food product is based on Risk Analysis as outlined by the Codex Committee on General Principles. Scientific risk assessment involves risk identification, characterisation and exposure assessment as defined in the Redbook[6]. This includes toxicological studies of pesticide residues, microbial contaminants, chemical additives and veterinary biologics.

In March 1995, a Codex sponsored joint FAO/WHO consultation proposed definitions for risk consideration activities in Codex (FAO/WHO 1995). The conclusions of this consultation were included in the 1996 CAC Progress report which clarified the definitions of risk, hazard, Risk Analysis, risk assessment, risk management and risk communication (CAC 1996).

At the 21st Session of the CAC (3-7 July Rome) amendments to the Codex Procedural Manual included four statements of principles concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account. The four statements of principle included:

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that standards assure the quality and safety of the food supply.
2. When elaborating and deciding on food standards Codex Alimantarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

[6] See Chapter 5 and Chapter 6 for a discussion of the Redbook's principles of Risk Analysis.

3. In this regard, it is noted that food plays an important role in furthering both of these objectives.
4. When the situation arises that the members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex (CAC 1995).

Economic interests supported these amendments. They were put forward by the US and supported by other agricultural exporters and many G77 nations and against the strong opposition of the EU and the Member State representatives in the EU delegation. The first principle was the major source of contention. It has been the traditional Risk Analysis approach of the Codex Alimentarius that risk should be scientific evidence of risk to human health. The EU was attempting to broaden the Risk Analysis approach to include broader concerns. The first principle, however, firmly supported the traditional scientific stance of Codex Risk Analysis. Although the second principle mentions the consideration of other legitimate factors, it is only within the parameters of the first principle that this is possible. That is, only those other legitimate factors that enhance the health protection of consumers from *identified* potential hazards may be considered. Further, the third principle reinforced the linkage between Codex and food trade. Therefore, the amendments to the procedural manual rejected the focus of food standards on broader concerns. Finally, the fourth principle pertains to the contentious role of Codex in risk management. Recall, risk management involves the evaluation of the risk identified in risk assessment in order to establish an appropriate regulatory response that reduces and prevents the hazard. Economic interests tend to argue that while an internationally harmonised approach to risk assessment is an appropriate role of the Codex, the response to risk is the domain of sovereign governments because risk management inevitably involves socio-economic issues that cannot be internationally harmonised. The pressure has been to create an opt-out situation so that a country may abstain from the Codex food standard decision, and the standard may still be adopted on the basis of its scientific justification. This is directly against the original intent of adopting standards by consensus and promoting the international harmonisation of food standards. Also, even if a country opts out of a Codex standard, the Codex standard would be considered the prevailing international standard under the SPS Agreement and would be relevant in the event of a trade dispute.

Generally it takes about seven years to develop a Codex food standard (i.e. one-half year for each steps (1)-(6) while steps (7) and (8) take two years each). There is a fast-track procedure which can be employed if the proposed standard is relatively uncontroversial. Under the fast-track approach, it is possible for the amended Draft Standard to be adopted at step 6 as a Codex Food standard, instead of being sent for further review, if consensus has been achieved.

While the Codex decision-making process is preferably done by consensus among national delegations although it can be by vote in the CAC if consensus cannot be achieved on very controversial issues, such as the use of hormones in beef production.

An important aspect of Codex standards is that they are subject to revision, as new scientific knowledge becomes available. It is the responsibility of each member country to present to the Commission and the relevant subsidiary committee new information that may require revision to a Codex standard. This information must, however, meet the Codex standards for a scientific justification.

Once a Codex Standard is developed, member countries are expected to adopt the standard into national food regulations in order to promote international consumer protection and market access rules. According to the Codex General Principles, there are three forms of member state acceptance: full acceptance, acceptance with minor deviations and free distribution. In this sense, the regulatory convergence strategy of Codex is one of regulatory co-ordination according to mutual recognition. The FAO and the WHO provide assistance to developing countries in establishing the capacity and knowledge necessary to implement food legislation congruent with the many Codex measures.

Along with standards, the Codex also develops and publishes codes of hygienic practice, codes of technological practice, guidelines and recommendations on various food safety and quality issues. The purpose of these measures is to protect the health of consumers in areas where standards may not be practical (FAO, 1998). The codes of hygienic practice provide industry with guidance on the safe production of food products. The codes of technological practice provide industry with guidance on the safe use of process, storage and transport technology during food production. Guidelines and recommendations are more general than the codes of practice, and provide industry with guidance on wider issues such as the procedures for food trade following accidental nuclear contamination.

To assist the Commission in ensuring consumer safety and health and protecting consumers from economic fraud, consumer organisations have participated in the development of Codex measures since 1965 (FAO, 1998; see also Houston, 1987). At the 20th CAC session it was recognised that the Commission must continue to provide an opportunity for consumer organisations to participate. However, it was reiterated that Codex decision-making is done by national delegations, therefore, it is the responsibility of the national delegations to involve consumers more effectively in the decision-making process at the national level in the National Codex Committees.

The Codex also includes, in Volume 1A General Requirements, a Code of Ethics for International Trade in Foods established in 1979 and amended in 1995. The Code is non-binding but applies to all foods traded. This code explains that the Codex goes beyond facilitating the removal of barriers to trade. Instead, it also encourages food traders to adopt voluntary ethical practices to protect consumers and to ensure fair trade. According to the Codex General Principles:

> *(i)nternational trade in food should be conducted on the principle that all consumers are entitled to safe, sound and wholesome food and to protection from unfair trade practices (FAO, 1998).*

Principally, the code is to prevent countries from exporting unsafe or poor quality food. It prohibits dumping of foodstuffs not suitable for the domestic market into foreign markets. Under the code, there are three responsibilities of the Party of Export. First, to employ as appropriate and practicable, legal or administrative controls aimed at preventing the exportation or shipment of food which does not comply with the laws of the Party of Import, or in the absence of applicable laws, with the Codex Alimentarius. Second, to promptly notify the Party of Import of the exportation of shipments of food found not to comply, when a legal or administrative means of preventing the exportation are not available or were unsuccessfully applied or where non-compliance was determined only after exportation. Third, to make available to the Party of Import, upon request, appropriate certification, inspection and other procedures as appropriate with the manner of compensation for these services to be agreed between the Party of Export and the Party of Import. If an importing country finds inappropriate imports, then it can request the Party of Export to pursue the exporter according to all legal and administrative procedures in order to rectify the situation, on behalf of the importer and the Party of Import.

Essentially, Codex is a top-down approach to developing universally acceptable food standards through its elaboration and consultation procedures at the multilateral level. It reflects a scientific rationality approach to regulatory development. Once a food standard is adopted by member countries, the Codex requests and the SPS and TBT Agreements require Members to incorporate the standard into any relevant domestic legislation. Under the principles of both Codex and the SPS and TBT Agreements, Members retain the right to unilaterally impose more stringent food safety regulations that may be deemed necessary to ensure domestic consumer protection. However, it is anticipated that when countries do deviate from the Codex food standard, they do so in a scientifically justifiable manner, where scientifically justifiable is measured with respect to the Codex Risk Analysis approach.

Concerns associated with linking the Codex with international trade agreements were the focus of a 1991 conference. The 1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade in co-operation with the GATT Secretariat, included several important proposed reforms to the Codex in order to make it more congruent with trade agreements. First, to accommodate the needs of trade agreements, it was proposed that the standards development process should be more rapid including a proposal for majority voting procedures. Specifically, it was proposed that a two-thirds majority vote in favour of a standard at stage 5 would be sufficient for the adoption of a standard. This departs from the Codex tradition of consensus based decision-making and shifts it towards judicious and timely decision-making in order to support trade interests. There was considerable support for this linkage even among the EU. Recall from the discussion on the SPS Agreement, economic interests who supported clarified international food safety rules dominated the EU's food trade policy.

Second, as the Codex Alimentarius is composed of standards, guidelines, codes of practice and recommendations, it was proposed that all types of Codex initiatives be considered as 'standards' under the trade agreements. This proposal was also included in the Report of the Twelfth Session of the Codex Committee on General Principles (CCGP) in 1996 (CAC, 1996a). In September 1998, the CCGP decided that with respect to the SPS Agreement all types of Codex initiatives are functionally the same. In April 1999, the CCGP decided that all types of initiatives were all 'food standards' according to the TBT Agreement as well. This decision was

on the basis of a TBT Committee recommendation that "governments harmonise their regulations on the basis of international standards and in the framework of Codex this applies to all the provisions which do not address the protection of consumers' health..." and "there is no difference between the various categories of Codex texts involved; for the purpose of the TBT Agreement all Codex standards and related texts correspond to the TBT definition of a standard"(Codex Secretariat, 1999).

Third, a proposal to increase the transparency of Codex was also included. Traditionally Codex was an international institutional arrangement dominated by technical discussions among leading scientists and food safety experts. Prior to its linking with the SPS Agreement, there was little reason for broader interest in the work of Codex. In this sense, Codex was not a deliberately untransparent institution, instead, there was no pressure for it to be accessible to interests beyond those interested in technical food standards issues.

The fourth proposal from the 1991 conference was to give priority to horizontal committees over vertical committees. That is, to move towards the development of general international standards or minimum requirements rather than numerous, specific vertical standards because the harmonisation of standards across specific categories was found to be very difficult and time-consuming.

Agricultural biotechnology and GM crops are dealt with under Codex on a product basis, not on a technology basis. In 1995, there was an unsuccessful attempt to permanently include foods derived from GM techniques on the agenda of the horizontal Codex Committee on Special Nutritionals. There is currently neither a vertical committee nor a horizontal 'general subject' biotechnology committee Instead, various vertical commodity and general subject committees address issues and concerns associated with agricultural biotechnology as it affects their traditional jurisdictions such as the Codex Committee on Food Labelling.

The use of biotechnology in food production emerged on the Codex agenda while considerable attention was focused on the EU-US dispute over beef hormones in the CAC meetings of 1991, 1993 and 1995. Further, at the CAC meetings of 1997, the use of bovine somatotrophin (rbST) was the controversial agricultural biotechnology issue on the agenda. Indeed, an important development was that the Commission did not approve the use of rbST on the basis that 'other legitimate factors' should be examined. In this sense, the early considerations of agricultural biotechnology and GM crops appeared to be very uncontroversial. Yet, in recent years, GM crops have

become an important, controversial topic of discussion and consultation in the Codex. GM crops raise two important issues for Codex. The first is determining what is the role of science in Codex standard-setting procedures while the second is determining what is the role of Codex in risk management procedures.

In 1990, a WHO/FAO Joint Expert Consultation (WHO/FAO, 1991) examined the issue of foods produced from GM ingredients and made seven recommendations.

1. GM (rDNA) foods should be evaluated for both safety and nutritional value.
2. New processes of production should be evaluated for safety.
3. Evaluations should have broad participation.
4. Evaluation can result in recommendations for animal testing.
5. Evaluation committee should have de facto authority over national policies on GM foods.
6. International organisations should harmonise risk (safety) assessments for both products and processes.
7. Consumer information should be scientifically based and only concerned with food safety issues.

These recommendations were crucial in forming a baseline approach for assessing and regulating GM crops. The first recommendation supported the product-basis for regulatory oversight, while the second recommendation suggested specific oversight in the instance of novelty. The third recommendation supported the need to include the 'social dimensions' in the regulatory development. The fourth recommendation encouraged more pharmaceutical-type assessment procedures for approval while both the fifth and sixth recommendations called for the development of a harmonised, international regulatory framework to GM crops overriding national regulations. The seventh recommendation only supported consumer information, such as labelling strategies, for food safety issues such as the possible presence of allergens and not for the consumers' right to know.

Also in 1990, the Joint Expert Committee on Food Additives developed risk assessment guidelines for the use of GM material additives in foodstuffs. The Medium Term Programme of Work for the period 1993 to 1998 included the development of Codex guidelines for the evaluation of foods produced from biotechnology and the application of risk assessment principles to the Codex work on agricultural biotechnology (Codex Secretariat, 1993). Unsurprisingly, these guidelines supported the scientific rationality approach to technology-based, novelty-based regulations.

In 1996, a Joint FAO/WHO Consultation on Biotechnology and Food Safety was held. The purpose of this consultation was to examine the broad implications of biotechnology on food safety and to propose Codex procedures for dealing with biotechnological applications.

At the 23rd CAC Session in Rome, 28 June – 3 July 1999, the United States proposed a 'Biotechnology Code' that clarified the dominant role of science in the food standards associated with products of biotechnology. This code, of course, supported the North American regulatory approach. Although unsuccessful, the CAC agreed instead to establish an Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology to examine the issues facing Codex efforts to develop biotechnology standards, codes of practice, guidelines and recommendations. The Task Force is wider in remit than the Biotechnology Code, as it will allow for broader non-science issues to be considered such as consumer and environmental protection issues. Specifically, the Task Force will:

1. elaborate standards, guidelines and other principles, as appropriate, for food derived from biotechnology;
2. co-ordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandates as related to foods derived from biotechnology; and
3. take full account of existing work carried out by national authorities, FAO, WHO, other international organisations and other relevant international fora.

The Task Force has a four-year mandate from July 1999 to July 2003 and it must present a preliminary report to the 24th CAC in 2001, a mid-term report to the CEC in 2002 and a Final Report to the 25th CAC in 2003 (AgraFood Biotech No. 19, 1999b). The first meeting of the Task Force was in Chiba, Japan 14-17 March 2000 and the issues covered included: establishing the scope and priorities of the Task Force, clarifying key concepts and definitions for core principles such as Risk Analysis and to examine national and regional experiences with the regulatory problems created by foods derived from biotechnology.

The Codex Draft Medium-Term Plan 1998 – 2002 also contains a proposal to establish Codex measures over the application of biotechnology. It requires 'consideration of a general standard for foods derived from biotechnology or traits introduced into foods by biotechnology'. Essentially, this means the formation of a

Codex horizontal General Subject Committee on biotechnology would have to be established.

In summary, the Codex employs a scientific rationality approach to the development and integration of food safety regulations supported by economic interests. Accordingly, the development of Codex standards for the use of biotechnology in food production has tended to reflect this approach. Yet, there is significant dissatisfaction with this approach and debates have emerged over whether or not the Codex can effectively hold the line on its traditional scientific approach. In this sense, the development of international biotechnology standards at Codex remains unstable and uncertain.

D. International Plant Protection Convention

Similar to the Codex Alimentarius, the International Plant Protection Convention (IPPC) is supported by economic interests because it follows a scientific rationality approach for developing regulations to protect plant health. The reason for this is because international scientific experts on phyto-sanitary hazards have dominated the development of international plant health regulations. This work has been carried out far from public view. The IPPC is important for economic interests because it is the only international institution that establishes international phyto-sanitary standards and their legitimate use according to the SPS Agreement. However, similar to the Codex, this is controversial because this approach contravenes the social rationality approach.

The Food and Agriculture Organisation of the UN administers the IPPC. Where the SPS Agreement is concerned, the IPPC standards are considered in the limited capacity for protecting the plant health of the domestic food supply from pests and disease. In this sense, IPPC standards may be used legitimately under the SPS Agreement to restrict imports of certain plants and products produced from plants because of the risk of transmission of diseases or pests to plants used in the domestic food supply. Hence, according to the SPS Agreement, the IPPC standards are for protecting the health of food supply plants, not for protecting overall plant biodiversity. In general, however, the IPPC is an environmental protection convention, despite its limited scope under the SPS Agreement. Therefore, while the IPPC's phyto-sanitary standards are crucial to the SPS Agreement from a more limited food safety perspective, they are really about environmental protection and, thus, the IPPC

straddles the divide between food safety and environmental protection measures. Consequently, the IPPC will be discussed first in its food safety context under the SPS Agreement, followed by a discussion of its environmental context in the next section on Environmental Protection and Trade (Chapter 3.2.2).

The IPPC is a multilateral treaty that was signed in 1951 and came into force in 1952. The scope of the convention is the protection of natural flora, cultivated plants and plant products. Similar to the Codex, the motivation for the IPPC was to develop international standards, applicable to all countries for the protection of plant health and, hence, remove the fragmented collection of standards in the various jurisdictions. To achieve this, the IPPC seeks to harmonise international measures designed to prevent the spread and introduction of diseases and pests to plants and plant products. Clearly, as the environmental biodiversity concerns about GM crops mostly include speculation on the risks, extent and consequences of vector-mediated, horizontal gene transfer between GM crops, non-GM or conventional crops, wild relatives and other natural flora and organisms, the scope of the IPPC is well positioned to focus precisely on these concerns.

Administratively, the IPPC is deposited with the Director-General of the FAO and administered through the IPPC Secretariat located in FAO's Plant Protection Service. One hundred and seven (107) governments are currently contracting parties to the IPPC. The Convention Secretariat, in collaboration with both regional and national plant protection organisations (RPPOs and NPPOs), provides a forum for the international co-operation, harmonisation and technical exchange of plant protection information.

The IPPC plays a vital role in international trade as it is the institution recognised by the WTO in the SPS Agreement as the institution responsible for developing international standards for phyto-sanitary measures affecting trade in plants and plant products. As a result, signatories to the convention agreed on amendments in 1997 in order to clarify its rules-setting procedures. The 1997 amendments, captured in the New Revised Text of the IPPC, include provisions that: formalise the role of the IPPC Secretariat; update the standards-setting procedures; emphasise co-operation and the exchange of information toward the objective of global harmonisation; and establish the Commission on Phyto-sanitary Measures (CPM). The CPM will serve as the global agreement's new governing body. The members of the Commission are the contracting parties to the Convention.

With respect to the international regulation of GM crops, the IPPC develops International Standards for Phyto-sanitary Measures (ISPMs). The ISPMs do not explicitly address agricultural biotechnology as a process. Instead, products of agricultural biotechnology that risk plant health are in-scope. In this sense, the risk assessment efforts of the IPPC have adopted the traditional trade principle of 'like' products or 'substantial equivalence'.

There are currently nine ISPMs accepted by the contracting parties to the convention that reflect procedural standards. The ISPMs include: Principles of Plant Quarantine as Related to International Trade; Guidelines for Pest Risk Analysis; Code of Conduct for the Import and Release of Exotic Biological Control Agents; Requirements for the Establishment of Pest-Free Areas; Glossary of Phyto-sanitary Terms; Guidelines for Surveillance; Export Certification Systems; Determination of Pest Status in an Area; and Guidelines for Pest Eradication Programmes. An important aspect of the ISPM's is that while they are based on a scientific framework of risk assessment, they tend to go beyond just providing risk information. Instead, they also include explicit risk management provisions in order to reduce and prevent plant health risks.

The development of ISPMs follows a three-stage procedure. First, suggestions to draft an ISPM are made by either the Secretariat, an NPPO, an RPPO, industry participants or by individuals. Draft standards are then developed and submitted to the Secretariat by the NPPOs or RPPOs. The draft standards are reviewed by the Committee of Experts on Phyto-sanitary Measures (CEPM), a group of phyto-sanitary experts from around the world that meets annually to review and comment on the suitability of documents prepared by the Secretariat. Alternatively, the draft standard may be reviewed by an international working group formed by the Secretariat. Recommendations to either develop an ISPM from the draft proposal or modify the draft proposal for further review are made. After the draft ISPM is developed, contracting parties and RPPOs are consulted. Comments are submitted to the CEPM and the Secretariat and a re-drafted standard is developed. This standard is then submitted to the Commission on Phytosanitary Measures (CPM) for approval and adoption as an ISPM. The Standard is published and distributed by the FAO.

The Convention is a legally binding agreement and member governments or contracting parties are expected to adhere to the ISPMs, but standards developed and adopted are not legally binding. Similar to Codex standards, measures that are based

on the international standards do not require supporting justification. Measures that deviate from international standards or measures that exist in the absence of international standards must be based on scientific principles and evidence in order to be considered as scientifically justified under the SPS Agreement. Emergency (or provisional) measures may be taken without such analyses, but must be reviewed for their scientific justification and modified accordingly in order to remain legitimate.

The most important initiatives of the IPPC, likely to have an impact on the international regulation of GM crops, are associated with the 1997 amendments to the convention. First, the creation of the Commission on Phyto-sanitary Measures (CPM), in effect, institutionalised the global role of the IPPC. The nascent Commission is scheduled to meet annually to establish priorities for standard setting and the harmonisation of phyto-sanitary measures in co-ordination with the IPPC Secretariat. Special sessions of the Commission may also be called. The functions of the Commission are to review the state of plant protection in the world, provide direction to the work programme of the IPPC Secretariat, and approve the ISPMs. In the sense, the IPPC must be considered an active player in the development and integration of GM crop regulations.

Second, the revised work programme of the IPPC Secretariat includes technical assistance through projects, including for emergency pest control and a forum for government consultation on shared concerns and for resolution of issues of contention, including trade issues. In other words, the IPPC has a built in agenda and mechanisms for dealing with phyto-sanitary risks to plant health.

Third, the Revised IPPC also prescribed specific obligations of member countries, including: to provide the IPPC Secretariat with an official Contact Point for the member country; to carry out regular pest surveillance and monitoring; to establish and maintain pest free areas; and to conduct pest risk analyses when scientific support for a phyto-sanitary measure may be needed. This requires pertinent data on pest biology, distribution, host range and potential for impact. From a risk assessment perspective, the IPPC supports scientific rationality approaches where contracting parties are obligated to be scientific in their approach to phyto-sanitary measures. To facilitate risk communication, a member government must appoint a Contact Point to provide communication, information sharing and transparency between contracting parties and the IPPC Secretariat.

Fourth, the 1997 amendments also formalised the link between the IPPC and the WTO because the SPS Agreement identified the IPPC as the organisation providing international standards for phyto-sanitary measures implemented by governments to protect their plant resources. Both agreements are distinct in their scope, purpose, and membership. Neither agreement is supplementary to the other. The IPPC makes provision for trade in a plant protection agreement by ensuring that phyto-sanitary measures have a scientific basis for their establishment and hence are not used as unjustified barriers to international trade while the SPS Agreement makes provision for plant protection from a food safety perspective within a trade agreement.

Unlike the Codex, the IPPC also has built-in provisions for dispute avoidance and dispute settlement in the event that measures are challenged as unjustified barriers to trade. In this sense, the IPPC has an important risk management role to play. With respect to dispute avoidance, the IPPC provides guidance, support, and information to contracting parties concerning phyto-sanitary measures and it facilitates the exchange of information between the parties with respect to regulatory requirements and pest status. The dispute settlement process under the Revised IPPC provides a neutral forum for a technical dialogue on the dispute. Countries first consult bilaterally with the aim of resolving the problem. The IPPC Secretariat provides technical support and facilitates the exchange of views and information in this process. If further action is deemed necessary, the disputing parties can request that the Director-General of FAO form an expert panel to review the situation and recommend a course of action. Although the dispute settlement process in the IPPC is non-binding, the results of the process can be expected to have substantial influence in disputes that may be raised to the WTO level under the SPS Agreement. This is because the IPPC Secretariat both nominates experts for WTO dispute panels and provides technical background to the panel. Once a dispute is brought to WTO, the decision will be legally binding and can have serious economic and political consequences. Therefore, the IPPC encourages governments to begin with consultation and a technical exchange with the aim of dispute avoidance at this technical stage before the political stakes are raised in a trade dispute.

Together, the Revised IPPC Text and the WTO SPS Agreement now ensure that there are structured channels for the establishment and notification of internationally harmonised phyto-sanitary measures as well as channels for notification of any member country deviations in the relevant measures.

There appears to be significant opportunity for the IPPC to enhance the international integration of GM crop regulations. First, the IPPC implements trade-related principles of plant protection and harmonises phyto-sanitary measures under the WTO SPS Agreement through multilateral negotiations among contracting parties or other relevant organisations. To this end, the phyto-sanitary standards developed by the IPPC aim to establish a rules-based approach to scientific risk assessment according to the principle of substantial equivalence.

Second, the IPPC Secretariat's regulatory integration activities remain consistent with the overall objectives of the FAO including: capacity building and strengthening plant protection infrastructures; dispute avoidance; updating and aligning plant protection legislation; and the provision of emergency assistance programmes. Hence, the initiatives of the IPPC are broader than just the development of scientifically-based standards. Instead, they also involve risk management activities focused on other legitimate factors such as the capacity gap. Indeed, the IPPC recognises that the North-South capacity gap remains a significant obstacle for international regulatory integration of phyto-sanitary measures. Establishing, implementing and monitoring compliance with ISPMs demands a requisite level of technological sophistication, arguably lacking in many less developed countries. To address this obstacle, a specific obligation of developed member countries under the Revised IPPC, is the provision of technical assistance on phytosanitary measures for Less Developed members.

An important unknown remains the effectiveness of the dispute avoidance and dispute resolution provisions of the IPPC. In the event that trade barriers to GM crops are supported by phyto-sanitary measures, then it is possible that the dispute provisions in the IPPC are used to resolve the social regulatory barriers rather than the WTO dispute settlement mechanism. However, the problem with the dispute settlement mechanism at the IPPC is that it thrusts the IPPC fully into the realm of risk management and top-down regulatory integration, rather than leaving it as an international forum for establishing science-based principles for risk assessment and for providing risk information. Technical decisions on risk management issues inadequately deal with the legitimate, broader concerns that risk management must also deal with. The IPPC dispute settlement decisions on appropriate domestic regulations will create winners and losers which in turn creates dissatisfaction among

the losers towards an international institution that is supposed to be developing consensual, co-ordinated phyto-sanitary measures.

In Summary, it is easy to understand why economic interests support the IPPC as the international organisation responsible for developing internationally harmonised phyto-sanitary standards. The IPPC can possibly play an important role in the development of an international regulatory approach to phyto-sanitary measures governing GM crops. Its remit to promote the health of natural flora, cultivated plants and plant products allows it considerable scope to cover the various environmental biodiversity concerns which have been levelled against GM crops. The IPPC has built-in dispute settlement provisions which avoid having to settle phyto-sanitary disputes at the WTO. This is a far more credible and legitimate forum to settle plant-related environmental disputes.

3.2.2 Environmental Protection and Trade

To date, much of the discussion on GM crops and trade has focused on the relationship between food safety measures and the rights and obligations of trade agreements (Isaac and Woolcock, 1999; Perdikis *et al.*, 1999). Yet, environmental biodiversity concerns are a big part of current consumer concerns about GM crops, and they create pressures to impose environmental protection measures that become social regulatory barriers. The trade threat is that the use of environmental protection measures is less disciplined under international agreements. Hence, it is important to understand how environmental protection measures are dealt with at the WTO. It will be argued that, in general, economic interests support a rules-based and science-based approach to environmental regulatory development and integration.

Generally, international food safety rules have been science-based while environmental protection rules have been less rules-based. Perhaps the most important reason for this situation what that the science of food toxicology tended to be more advanced than the science of predictive ecology, essentially limiting the extent to which environmental regulatory development could rely upon science. However, with the Uruguay Round Agreement, economic interests have, in fact, begun to formalise environmental protection measures under science-based trade rules. This has come about in two distinct ways. First, there has been an attempt to clarify safety-related environmental measures under the SPS Agreement's link to the IPPC and to clarify non-safety-related environmental measures under the TBT Agreement. Second, there

has been an attempt to demarcate the line between trade agreements and multilateral environmental agreements. These will be discussed in this order below.

A. Processing and Production Methods (PPMs)

The traditional focus of GATT 1948 was on products, not processing and production methods (PPMs) because products are traded and cross international borders. Increasingly, however, it became clear that that the manner in which a product was processed or produced was relevant to domestic regulations and hence international market access. For instance, the PPMs used in a particular industry may generate negative environmental externalities (i.e. pollution) which can indiscriminately cross international borders and pollute the global common. While recognizing the importance of PPMs in trade measures, the international trade regime sought to clarify the legitimate use of such measures. What has emerged is a two-pronged approach for dealing with PPM-based environmental measures. Safety-related PPM-based measures are addressed under the SPS Agreement through the IPPC, similar to the way food safety measures are addressed under the SPS Agreement through the Codex. Non-safety-related PPM-based measures are addressed under the TBT Agreement. The key point is that, similar to food trade issues, the economic interests behind the trade regime have sought to disentangle safety measures from non-safety measures and make the former science-based and latter subject to the traditional trade principle of non-discrimination.

Under the SPS Agreement, economic interests have formalised the use of safety-related phyto-sanitary PPM-based measures in the international trade regime. This is very important for social regulatory barriers imposed on GM crops and justified as necessary to protect the safety of domestic environmental biodiversity. Such trade-restricting measures would be subject to the IPPC scientific risk assessment procedures. In this sense, the scientific rationality approach now covers safety-related PPMs. Phyto-sanitary measures imposed by Members would be subject to the scientific justification requirements outlined in the IPPC. The phyto-sanitary standards and standards-setting procedures must be considered as the parameters for the permissible phyto-sanitary measures that Members can legitimately adopt. This creates a rules-based and science-based approach to safety-related environmental protection regulation similar to the Codex approach to food safety regulation.

Non-safety-related PPM-based environmental measures are not subject to the same degree of scientific justification as safety-related measures. Without this scientific basis, non-safety-related measures are disciplined under the TBT Agreement according to the traditional trade principle of non-discrimination. With respect to environmental measures pertaining to GM crops, the main TBT issue is the permissible use of non-safety trade-restriction measures based on the PPMs employed in the extraction, harvesting or manufacture of traded goods.

The relationship between non-safety-related PPMs and international trade was investigated in both the Tokyo and the Uruguay Round. In the Tokyo Round CPs differed as to how they thought PPMs should be dealt with. On one hand, some CPs including major agricultural exporters sought to have PPMs included in the TBT Code to prevent circumvention of the GATT trade principles by technical regulations. The aim was not to prevent the use of PPMs in product standards such as labelling requirements, but to have some discipline on their use. Other CPs did not want to have PPMs included in the Code and the result was a two-fold compromise. First, PPMs were divided into two types; product-related PPMs and non-product-related PPMs (OECD 1997c) to reclaim some of the traditional division between products and processes under the GATT. Second, to subject the use of PPMs to the dispute settlement provisions of the TBT Code (TBT Code, Article 14:25).

In the Uruguay Round, the US along with other agricultural exporters again tried to have PPMs disciplined under the TBT Agreement. By the end of the round, the only change was that product-related PPMs would be covered by the TBT Agreement, not non-product-related PPMs. This means that the rights and obligations of the TBT Agreement only apply to those PPM measures that have an effect on the safety or quality attributes of the final product. This is similar to the SPS Agreement, which focuses only on the safety of imported materials, either final food products or food inputs. Accordingly, there are no permissible circumstances for employing non-product-related PPMs. As will be shown below (Chapter 5), GATT and WTO dispute decisions have concluded that trade restrictions based on the non-product-related PPMs of traded goods violate the trade principles of non-discrimination and they result in an unjustifiable extra-territorial extension of one Member's environmental preferences upon another Member.

With respect to food trade, product-related PPMs can include, for instance, the type of veterinary practices and quality assurance systems that may be employed in a

beef production system because these PPMs may affect the safety and quality of the final beef products. That is, product-related PPMs are associated with the consumption or use stage of the product and may cause negative consumption externalities. According to the TBT Agreement, coverage includes "product characteristics or their related processes and production methods" but only as they avoid "consumption externalities" (TBT Agreement, Annex 1). Therefore, only consumption externalities associated with product-related PPMs are within the scope of the TBT Agreement. Further, and similar to the SPS Agreement, there are limits to the permissible use of product-related PPM-based measures that Members may enact. Under the TBT Agreement the legitimate deviations are not as precise as the SPS Agreement and can include "different social objectives and priorities attached to environmental protection" (OECD, 1997c).

On the other hand, non-product-related PPMs in the trade of agricultural crops are generally associated with the agronomic system, but have no influence on the end product. For instance, the technologies employed or the soil cultivation or conservation strategies used are non-product-related PPMs. Although not responsible for consumption externalities, these PPMs may cause negative production environmental externalities. Yet, these PPMs are out of scope of the TBT Agreement, and are the sovereign domain of the Member government. From a trade perspective, such measures must follow the principles of non-discrimination.

The problem with non-product-related PPMs and agricultural crops from an environmental protection perspective is that the pursuit of sustainable development and the protection of biodiversity focus on production externalities and result in pressures on domestic governments to establish environmental protection measures pertaining to non-product-related PPMs which can become regulatory market access barriers. Specifically, GM crops are associated with concerns about their impact upon the environment and this concern has led to opposition in Member states to the domestic environmental release of GM crops. It is reasonable to suppose, however, that this may even lead to a Member enacting trade measures based on the non-product related PPMs of GM crops grown elsewhere and imported into the Member country.

In the Uruguay Round, most developing countries did not want any linking of trade and the environment because often PPMs are considered to be a source of comparative advantage. They point out, with some justification, that the industrialised

countries developed without environmental controls. Now that they have all the benefits conferred by industrialisation, especially higher incomes, they can afford to demand more income elastic environmental protection through PPM-based trade measures. This makes the industrialisation process harder for the South. Such measures may favour particular PPMs or technologies that are not employed and/or not available to developing country producers. Also, products crucial to developing countries (i.e. paper products/timber) are disproportionately covered by PPM measures. In other words, if PPMs favour new technologies, then the capacity gap means that the less technologically advanced will continue to lag behind.

Despite the importance of the issue, the compatibility of PPM-based environmental measures with the rights and obligations of the TBT Agreement remains uncertain (Caldwell, 1998). Moreover, with respect to GM crops, an additional unresolved issue exacerbates the trade uncertainty. It can be expected that this issue will be an important focus of the TBT Committee as trade issues associated with GM crops arise.

There is significant uncertainty about whether or not GM crops can even be categorised as having different PPMs than conventional, non-GM crops. Consider that genetic modifications are made to the cells of the crop, which are then cultured into seeds. In the case of production trait varieties, the GM crops are then grown in the exact same agronomic system as the conventional varieties. Then the crops are harvested and sold into the same processing and distribution system as non-GM varieties. Accordingly, GM crops which do not require a new or different agronomic or processing systems would not be grown under process or production methods different than conventional crops and there would be no difference in the non-product-related PPMs of GM crops and non-GM crops. As the approved GM varieties to date have been approved as like products or as substantially equivalent, there are no differences in product-related PPMs either and there are no consumption externalties to consider. In this case, the TBT Committee will have to decide on, first, the applicability of PPMs to GM crops in the first instance, and second, on the legitimacy of the principle of substantial equivalence.

Of course, the TBT Committee does not have to proactively make this decision. Instead, it could allow differences of opinions among Members to escalate from social regulatory barriers, to trade tensions, followed by trade disputes brought to the WTO's dispute settlement body. In Chapter 5, several WTO disputes based on

food safety and environmental protection measures are examined, in order to extrapolate how the dispute settlement body may deal with such GM crop controversies.

B. Trade and Multilateral Environmental Agreements

In November 1999, the WTO's Committee on Trade and the Environment (CTE) published a report on the environmental effects of trade (Economist, 9 Oct. 1999). The report acknowledges that although trade, per se, is not harmful to the environment, it is not beneficial in all cases. The report concurs with environmental concerns on four issues. First, subsidies for export-oriented commercial activities such as farming, fisheries and subsidies for fossil fuel driven activities create incentives for economic activities that are not congruent with sustainable development. Second, voluntary third-party eco-labels are a valuable tool for providing consumer information about the use of acceptable non-product-related PPMs. Third, the CTE supports a comprehensive review by Members on the environmental effects of trade in order to increase the transparency of environmental concerns. Fourth, the CTE recognises that the WTO, although accountable to Member governments, is not accountable or transparent or accessible for non-Members, such as environmental organisations. The report suggests that the WTO must address these four areas if it is to address the harsh criticisms levelled against it by environmental organisations.

The report does recognise, however, that the primary goal of the WTO is to enhance trade liberalisation and that the WTO is not the proper venue for environmental concerns. For instance, first-best environmental policies, not second-best trade policies, must tackle negative environmental effects at source. Consequently, the report concludes that trade rules, in pursuit of free trade, cannot be altered to accommodate environmental objectives. In this sense, there is only so much that the WTO is able and willing to do to meet environmental objectives. These limitations often give rise to negotiations for multilateral environmental agreements (MEAs) outside the WTO framework. MEAs and their relationship with trade will be examined next.

Multilateral Environmental Agreements (MEAs) are inter-governmental agreements on environmental objectives that reflect a regulatory co-ordination strategy of social integration. Their relationship with the traditional trade approach is

crucial to understand, because generally the social rationality approach prefers the deeper social integration of the MEAs over the shallow, economic integration of trade agreements.

MEAs or the smaller regional environmental agreements (REAs) generally focus on the non-product-related PPMs that are outside the TBT Agreement. There are about 180 and they include the Kyoto Protocol, the Basle Convention on the Transboundary Movement of Hazardous and Toxic Waste and the Montreal Protocol. Generally, MEAs are agreements between like-minded countries. It has been argued that MEAs require a shared view of environmental harm that is often based on "moral values, ethical or cultural preferences or environmental choices which lack a scientific basis" (OECD, 1997). Also, as the demand for environmental protection measures is income elastic, they tend to be supported by higher-income, developed countries while LDCs generally view them as a threat. As mentioned, the reason for this is comparative advantage (OECD, 1993). Many LDCs view their PPMs as a source of advantage and resist the idea of limiting this advantage through MEAs.

MEAs, through ex ante regulatory co-ordination efforts aim to focus domestic environmental policies on agreed global objectives such as ozone depletion. MEAs tend to come into conflict with trade only when non-signatories are affected by the obligations that have been negotiated by signatories. For instance, a trade dispute requires a complaint to the WTO. Members can have and keep policies that contravene the rights and obligations of WTO Agreements provided no other Member complains. Signatories to a MEA would all share the same environmental protection philosophy so that even if domestic environmental regulations in one signatory are trade restricting other signatories would not complain because they appreciate the broader environmental objective. A non-signatory, however, who does not share the same environmental protection philosophy but is affected by the trade restricting measure is more likely to complain about the measure to the WTO.

Yet, the problem with MEAs is not always between signatories and non-signatories. The Biosafety Protocol (discussed in Chapter 4.2) is an example of the difficulties that arise when MEAs encroach upon international trade. During negotiations, the Biosafety Protocol threatened to have significant impact upon the trade of GM crops, and as a result the Miami Group of agricultural exporting signatories effectively blocked agreement of the protocol in February 1999, indicating the dominance of trade concerns over environmental concerns.

Additionally, MEAs are based on consensual negotiations involving wide participation, which is a time-intensive process. It is unlikely that a MEA can be negotiated rapidly enough to deal with the environment and trade concerns arising from PPM-based environmental measures in order to curtail the pressure for unilateral action and a trade complaint to the WTO.

As mentioned, the CTE has investigated the relationship between MEAs and the rights and obligations of the trade agreements. Specifically, it has examined the permissibility of non-product-related PPM-based measures that differentiate between physically or functionally similar products that exhibit no consumption externalities.

3.3 Conclusions

In this Chapter, the regulatory development and regulatory integration approaches for GM crops supported by general economic interests were examined. It was revealed that at the heart of the support is the demand for certain and predictable rules for the development, commercialisation and international market access of GM crops. Congruent with the economic perspective and the scientific rationality approach, economic interests support the correction of real market failures permitting economic growth and development, which in turn lead to higher income elastic social regulations.

Economic interests support regulations that ensure technological progress through capacity building. Capacity permits the development and commercialisation of GM crops, securing both private and public economic gains. Economic efficiencies are gained through the vertical and horizontal integration of the GM crop applications.

The commercialisation of GM crops requires stable and predictable regulatory rules and economic interests support a science-based framework for these rules. This includes rule for product development, testing, field trials and market approval as well as rules for intellectual property protection.

In addition, as commercialisation at the international level is required to recoup R&D costs, they also support international market access rules congruent with a science-based framework. They support the WTO approach to clarifying the trade compliant use of food safety and environmental protection measures through the SPS Agreement and its links with the Codex and the IPPC. The key feature is that the traditional trade approach attempts to disentangle safety-related measures from non-safety-related measures. In order to be considered legitimate, safety-related food and

environmental protection measures must be scientifically justifiable, while non-safety-related measures must meet the trade principle of non-discrimination.

The traditional trade approach as outlined in the WTO Agreements such as the SPS and the TBT Agreements, along with the accompanying international institutions, such as the Codex and the IPPC, provides a coherent approach to international regulatory development and integration. Member countries may unilaterally impose social regulatory barriers to GM crops, but only with appropriate scientific justifications.

CHAPTER FOUR SOCIAL INTERESTS

In the previous chapter, the regulatory development and integration approaches supported by economic interests were examined. It was argued that these interests have dominated the development of the international trade regime with the result that it reflects a scientific rationality, rules-based framework encouraging regulatory competition among Members. Yet, in recent years, this framework has come under considerable criticism from non-economic or social interests who support a much different approach to regulatory development and integration.

The objective of this chapter is to examine the regulatory development and regulatory integration regimes supported by the social interests in order to understand their criticism of the traditional trade diplomacy approach. Broadly, this group is composed of various national and international non-governmental organisations. Three types of social interests may be identified according to the consumer concerns that they predominantly focus on: consumer, environmental and social development interests. This is, however, only an illustrative categorisation. In most cases it is difficult to define social interest groups neatly as one of the three types because regardless of their primary mandate, many of the groups include consumer, environmental and social development advocacy.

It will be argued that social interests support regulatory development and integration approaches that are socially responsive. That is, they support the social rationality approach to regulatory development and a regulatory co-ordination approach to regulatory integration.

4.1 Regulatory Development and Integration

Prior to discussing each of the social interests separately, it is important to note that all three tend to share an important focus on the social rationality approach to regulatory development and integration. Social interests reject two important premises of the economic perspective. First, economic analysis generally assumes that technology and innovation are crucial elements of economic growth and social welfare[1]. Social interests argue technology is not an inherent factor in social welfare.

[1] Although not all economists hold this view. For a insightful discussion of the 'steady-state' or zero growth economy see H. Daly (1997) 'Towards a New Economics: Questioning Growth' excerpted from

Instead, it is the application, management and distribution of technology that can lead to increases in social welfare or in the case of misapplied, mismanaged and poorly distributed technology, decreases in social welfare. Second, the economic perspective tends to treat consumers as economic agents, where price is the only aspect of GM crops that they are concerned about. If prices fall, there are consumer welfare gains (i.e. Moschini *et al.*, 1999). Social interests argue that this does not provide an accurate picture because consumers have legitimate concerns beyond just economic concerns. And in the UK, these concerns have lead to consumers actually spending more on food purchases in order to avoid products made from GM crops and to, presumably, increase their welfare (to be discussed more fully in Chapter 7.3.1).

Accordingly, the social interests argue that regulatory development must not simply be an exercise of correcting market failure in order to maximise technological progress. It must be responsive to social preferences and concerns, regardless of the economic rationality of those concerns. In addition, regulatory integration must be sensitive to divergent social normative frameworks between jurisdictions and must avoid sacrificing the social dimensions to the pursuit of economic efficiency and competitiveness; creating a so-called 'hollowing-out' of the nation-state (Picciotto, 1996). To avoid this, social interests support a regulatory co-ordination approach to deeper integration.

There are five similarities between the three types of social interest groups that are relevant to the development and integration of GM crop regulations. First, they hold a particular belief system or frame of reference, which tends to be based on normative beliefs that are not subject to scientific rules of evidence and debate. The belief systems of the three types of social interests will be discussed separately below, but it is important to note that some organisations can feel so strongly about their normative beliefs that they are willing to take illegal action, as evidenced the by the destruction of UK field trials of GM rapeseed (see Chapter 7.3.1). Further, the strength of the belief system may effectively limit the ability of social interest organisations to participate in activities that demand compromise. For instance, it has been argued that German environmental groups in a 1991 Participatory Technology Assessment of herbicide tolerant GM crops "had ambivalent feelings about being involved in a procedure in which they could not control the finding" (van den Daele *et*

'Toward a Stationary-State Economy' in J. Harte and R. Socolow (Eds.) Patient Earth (New York: Holt, Rinehart and Winston, 1971) (http//csf.colorado.edu/authors/hanson/page41.html).

al., 1997). In fact, van den Daele *et al.* (1997) note that these organisations withdrew from the Participatory Technology Assessment and released their version of the findings prior to the release of the final, consensus-based report. In contrast, economic interests tend to have fluid belief systems reacting to market demand signals so that when demands change, economic policies change as evidenced by the shift to non-GM ingredients among UK supermarkets (see Chapter 7.3.1)

Second, for social interest organisations the public is the audience and these organisations tend to be very effective at conveying their position to the public in an easily understandable manner. These interests have traditionally not held much trade policy power. Indeed, to increase their policy voice, they have found populist and sensational ways to influence policy in an effort to circumvent traditional trade diplomacy channels. Hence, social interest organisations are important actors in shaping public opinion, which in turn has important influence upon regulatory development and the prospects for regulatory integration. The public-orientation of these organisations is in conflict with the traditional trade diplomacy strategy of closed-door negotiations that are neither publicly transparent nor accessible. It is also in contrast to the typical scientific rationality approach used, for instance, by the international scientific community (i.e. Codex and the IPPC), whose work is undertaken far from the public view and at a technical level not easily understood.

Third, they share the objective of promoting sustainable development and encouraging activities that promote sustainable development is an issue to which all three types of organisations converge. There has been a general international shift in the interpretation of 'development' as a goal of government policy. The traditional view of development is rooted in the economic perspective of continued growth and prosperity permitting higher income elastic social regulations. Now, development has taken on a decisively socio-economic character as it is now termed 'sustainable development'; interpreted as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs"(World Commission on Environment and Development 1987). While this term does lack precision it is understood to mean a shift in policy focus from just the *economic* to the *socio-economic* gains.

Fourth, the social interests share concerns, in general, about democratic deficit and accountability issues associated with international institutions. For instance, social interest organisations have limited resources for which to participate in the myriad

international institutions for GM crop regulatory development (i.e. WTO, Codex, IPPC, OECD, etc.) and they are concerned that their perspective may not be appropriately addressed when international standards are being developed. This concern was given credence at the 1999 G7/G8 Summit in Koln, Germany where the Transatlantic Business Dialogue (TABD, see Chapter 5) was allowed to participate but the Transatlantic Consumers' Dialogue (TACD) and the Transatlantic Environmental Dialogue (TAED) were not allowed to (TACD, 1999).

The fifth concern of the social interests lies with the international economic integration approach of traditional trade diplomacy. They do not support the WTO as the dominant international institution for the integration of food safety and environmental protection regulations because they believe that it fails to deal appropriately with the social rationality approach. In fact, a recent petition headed by the environmental group Friends of Earth and signed by over 1200 other social interest groups from 85 countries was presented at the 1999 G7/G8 Summit in Koln, Germany (Independent, 10 October 1999). The petition demanded a complete review of all the WTO's Uruguay Round commitments prior to embarking on another round of multilateral trade negotiations. They argue that the problem is that the WTO is "built on an outdated model of swapping tariffs, when it should really be based on a competition-based system of regulation and liberalisation" (Evans, 1999). Also, the dissatisfaction of civil society with 'forced' regulatory integration through the trade approach of regulatory competition has been incisively summed up, with respect to the Appellate Body decision in the beef-hormones dispute:

> *The WTO Dispute Settlement Body has, inter alia, placed the World Trade Organisation in charge of determining the legitimacy of domestic health regulations; misinterpreted the provisions of the SPS text allowing countries to determine the level of appropriate risk for their citizens; favoured frequently lower international standards over higher domestic standards; dismissed the precautionary principle as a legitimate basis for health and environmental policy; and, destabilised the international trade regime by inserting itself into a dispute in which it lacks the necessary expertise and competence to adjudicate (Caldwell, 1998).*

The general rejection of the WTO's regulatory integration approach and its perceived failure to adequately deal with broader, social concerns such as sustainable development has resulted in a dramatic convergence of opposition to the WTO manifested in widespread protests at the 1999 Ministerial meeting in Seattle. In contrast to the WTO regulatory integration approach, is the social integration approach exemplified by the Biosafety Protocol. This protocol has been widely supported by social interests and its negotiations and structure will be examined below, following the description of the three types of social interest organisations.

Despite the similarities, however, it is inaccurate to portray consumer, environmental and social development organisations as a homogenous group. Instead, there are important differences among them. In fact, these differences raise doubts about the compatibility of their belief systems and the potential for a lasting, cohesive opposition to GM crops. Below is an assessment of social interest organisations that have recently played very public roles in the policy debates associated with the development and integration of GM crop regulations. This assessment is intended to be an illustrative survey and not a comprehensive catalogue. In addition, the discussion will primarily focus on those organisations that are international, but many national organisations have also established an effective presence in the regulatory policy debates so that the distinction between international and national social interest organisations has become blurred.

4.1.1 Consumer Organisations

The differences between the three types of social interest organisations are especially distinct between consumer organisations and the other two. Consumer organisations advocate a comprehensive range of consumer objectives, including both economic and social concerns. Consider the four types of consumer concerns associated with GM crops (from Chapter 2.2.1). Consumer organisations have a traditional focus on the consumer's economic concerns. They have long sought to ensure competition in markets, bringing the economic benefits of reduced price and improved quality, choice and service. Yet, while the economic concerns remain important, consumer organisations have never lost sight of the fact that consumers are not just economic agents. Consequently, they have also traditionally balanced the economic objectives with consumer health and safety objectives. The focus on sustainable development has also brought environmental biodiversity concerns fully

into the agenda of consumer organisations. Finally, social norms including moral, ethical and even religious concerns have played an important role in establishing the policy parameters within which the economic objectives of consumer organisations are pursued. Therefore, consumer organisations have first-hand knowledge of the difficulty associated with balancing economic and social interests. In fact, the comprehensive range of objectives is precisely why consumer organisations in general support freer trade because of the economic benefits of competition. Yet, increasingly this support is qualified. Freer trade must not come at the expense of lower standards for food safety and environmental protection. The other two types of organisations, on the other hand, are more singular in purpose and don't face the same kind of balancing act.

Consumer organisations essentially have two primary objectives associated with the regulation of GM crops. First, to ensure that regulatory development is fully focused on the consumers' right to know and second, to ensure the democratic accountability and transparency of international regulatory integration strategies focused on deeper, social integration. Among these organisations, neither trade nor GM crops are bad per se, and in fact, most consumer organisations are not calling for a complete moratorium on GM crops. Instead, they view that the 'economic' perspective in favour of technological progress, national competitiveness issues and regulatory competition is at the expense of stringent consumer and environmental regulations. They argue that when consumers have concerns about a product like GM crops regulatory development and integration must be socially responsive enough to react to these concerns regardless of the economic rationality of such a regulatory reaction. Moreover, they argue that international institutions charged with developing international standards, such as Codex, cannot just be accountable to national governments because national governments, lobbied by industry and in pursuit of competitiveness, may collectively ignore broader consumer concerns. Nor can they be only science-based in the face of a large information gap and credence concerns. Essentially, the consumers' right to know about perceived risks must be the primary focus, regardless of the lack of scientific justification for such a regulatory response.

Consumer organisations tend to share the same positions on trade and GM crops in both North America and the EU, despite the asymmetrical consumer acceptance. In the EU, the European Consumers' Organisation, BEUC, argues that the primary goal of the EU's GMO regulations (90/220 Directive) should be to satisfy

consumer concerns and "thus, encourage consumer acceptance" (BEUC, 1999). This includes demands for greater consumer consultation at all stages of the GM crop approval process. The UK-based National Consumers Council argues that Codex must be committed to a full freedom of information policy and greater consumer participation in expert committees (NCC, 1998). Similar demands can be found in North America. The US-based Consumers' Choice Council argues that the consumers' right to know must be the dominant justification for labelling schemes (CCC, 1999). The Consumers' Association of Canada argues that consumer concerns however broad should dominate regulatory development through wide participation (Consumers' Association of Canada, 1994). More recently, the Transatlantic Consumers' Dialogue (TACD), has argued for assurances that trade liberalisation will not compromise high food safety and environmental protection standards and that negotiations will encompass the broader concerns of consumers, rather than be focused on traditional trade interests (TACD, 1998). With respect to GM crops, the TACD has argued for a mandatory labelling scheme based on the consumers' right to know in Codex standards-making procedures (TACD, 1999b).

Therefore, consumer organisations tend to call for greater democratic participation and accountability of regulatory and trade policy development within international institutions. This includes greater participation of all stakeholders, not just scientists and national delegations, in the formation of international standards and in trade dispute decisions. They also call for consumer and environmental safety regulations that keep pace with technological innovation while remaining focused on the consumers' right to know (Evans, 1999; BEUC, 1999; CCC, 1999; Consumers' Association of Canada, 1994).

Notable consumer organisations involved in issues of trade and GM crops include:

- Consumers' International: observer status at Codex
- International Association of Consumer Food Organisations (IACFO): observer status at Codex
- BUEC (European Consumers' Organisation):
- Consumers' Choice Council (US): an association of US-based NGOs across all three types; consumer, environmental and social development organisations.

- Consumers' Association of Canada

4.1.2 Environmental Organisations

Environmental organisations differ from consumer organisations because of their traditional focus on a single objective - environmental protection. With respect to the four types of consumer concerns, environmental organisations target almost exclusively the environmental biodiversity concerns associated with GM crops. Unavoidably, of course, both human safety concerns and social norms also influence the position of environmental organisations. Yet, this position often disregards the legitimate and crucial economic factors. The benefit of having a virtually singular objective is that positions are not balanced between competing objectives. Instead, environmental protection is more of a belief system based on sustainable development, which tends to be incongruent with compromise or concession.

There are two general aspects of the environmental belief system, which are relevant for the international trade of GM crops. The first is that according to the belief system trade liberalisation and sustainable development objectives are not compatible. There have been many calls by environmental organisations for a revision of the WTO to focus less on trade liberalisation and more on sustainable development. In the event that the two objectives clash, they hold that environmental principles should dominate trade principles. Without such a shift, it is argued that the WTO should be dissolved, or at least ignored.

The second is that intensive agricultural production is incompatible with sustainable development objectives. Most environmental organisations support, instead, an organic system of production. Hence, GM crops targeted to the intensive agronomic system contravene the belief system in principle, regardless of the attributes of these crops. The result has been calls for complete bans or moratoriums on the technology because it has been commercialised for the intensive agricultural system. Environmental organisations in the UK have suggested that the UK government must decide between either organic production or GM crops in an intensive system. Yet, from a regulatory policy perspective this belief is problematic. Basically, there has been insufficient justification as to why GM crops and organic production are mutually exclusive. The real choice is between organic and intensive, not between organic and GM crops. GM crops have simply become the vector of concern because of their application. Indeed, it has been easy to cynically portray

them as products of faceless mulitnational corporations designed for the intensive system. This portrayal fails to capture reality. Significant international research and commercialisation efforts are underway to develop GM crops to meet pressing economic, human health and biodiversity needs in both developed and in less developed countries. Moreover, GM crops can facilitate, and indeed have facilitated, a shift away from the agro-chemical paradigm of the intensive system, hence, facilitating more sustainable agriculture.

In summary, from the environmental perspective it is argued that GM crops are being developed by multi-national corporations who play by the trade rules of the WTO and who have developed the crops to fit into an intensive agricultural system (Ecologist, 1998). Yet, lying within this criticism is a crucial policy issue. Clearly the concern lies not with the technology per se but with the way it has been applied and, more importantly, who has applied it. Many wish to see the development of a strong, rules-based international institution, such as the BSP, with a global sustainable development remit that dominates trade liberalisation efforts, responsible for establishing socially responsive regulations that employ the social rationality approach.

Notable environmental organisations in opposition to GM crops include:

- Friends of the Earth (International with regional offices)
- Greenpeace (International with regional offices): early support from Greenpeace Europe for GM crops in the development of a renewable and biodegradable credit card, yet had to abandon support as it may have lent credibility to Monsanto and GM crop technology.
- World Wildlife Fund for Nature (International)
- Sierra Club
- European Environmental Bureau
- Genetix Snowball (UK)
- Research Foundation for Science and Technology (India)
- Grass Roots Environmental Effectiveness Network (GREEN)

4.1.3 Social Development Organisations

Social development organisations, as the name suggests, focus on social development at the national, regional and/or international level according to a

particular normative belief system. In this sense, they begin from the fourth type of consumer concerns (moral, ethical and religious concerns) and this foundation then shapes the social development policies. Similar to environmental organisations, social development organisations are dissatisfied with the international trade of GM crops, although the reasons differ. With respect to trade and the WTO, they believe that the rules for international trade are designed to benefit the industrially powerful at the expense of the industrially weak and they argue that the WTO has become a vehicle for multinational corporations to dominate global production (Independent, 10 October 1999). In other words, they support trade liberalisation if it were used explicitly to prise open the affluent markets of developed countries so that producers in less developed countries could earn foreign currency.

Consequently, with respect to global development, they argue that the international trade of GM crops furthers the divide between the north and the south. The socio-economic implications of agricultural biotechnology upon development are explicitly linked with capacity and developing countries have much at stake. Agriculture is often the largest sector in terms of income, employment and foreign exchange earnings. While some argue that GM crops will be beneficial for the economic prospects of developing countries, others argue that they will have serious adverse impacts upon development.

Some supporters of GM crops have promoted a *global welfare promise* of GM crops. They argue that that agricultural biotechnology will greatly enhance agricultural productivity in less developed countries. Indigenous seed varieties can be specifically modified to the ecological conditions challenging production resulting in greater yields of better quality with a reduced need for chemical treatments. An economic study of the adoption of GM virus resistant potatoes in Mexico concludes that GM crops can be conducive to and beneficial for small-scale farming operations in LDCs (Qaim ,1999). From an economic development perspective, agricultural productivity may be increased without the environmental degradation of land conversion and chemical treatments. Environmentally sustainable agricultural production can meet the food demands of a rapidly increasing global population. The argument follows then, that less developed countries should be assisted in building capacity in order to reap the significant benefits from GM varieties. Other potential gains for developing countries include revenues generated from the use of their biodiversity by researchers from developed countries.

Social development interests argue that there are problems with this *global welfare promise* (Kneen, 1999; RAFI, 1998; Shiva, 1985). First, the leadership of the private sector in agricultural biotechnology means that much of the *knowledge* is proprietary and will not be shared without compensation, a price many producers in less developed countries cannot afford. As a result, the overwhelming majority of GM crops have been developed to meet the needs of developed country producers; those who can afford to pay for the technology.

Second, most developing countries lack the current scientific capacity necessary to be involved in GM crop development[2]. This is not just an issue of technology transfer because these countries tend to lack the educational infrastructure to adapt scientifically, let alone the financial infrastructure to support competitive, private agricultural biotechnology ventures. The dynamic scale effects of increased potential for new GM varieties combined with decreased time for product development suggest that the capacity gap will only increase. Further, the capacity gap limits the possibility of developed countries relocating their research and development efforts to a developing country in order to share the knowledge. In fact, an alarming development from the perspective of global economic development is the potential import substitution of traditional exports from less developed countries. For instance, recent research efforts on canola (rapeseed) in both the US and Canada have focused on modifying the oil content of the seed to express the characteristics of palm oil. However, several developing nations rely heavily upon palm oil exports as a source of foreign currency.

Indeed, it appears that the potential economic development problems with GM crops for LDCs are institutional problems of access to and the distribution of technology. As agriculture increasingly becomes a high-technology industrial sector, driven by private firms, the competitive disadvantage of developing countries is likely to grow, with a dramatically decreasing likelihood for these countries to catch-up. Since knowledge is the key, industrial imitation is not possible as it was in other high-technology sectors of the past. In order to prevent such developments, institutional reform in both developed and developing countries, focused on capacity-building, technology transfer and the targeting of innovations to the production problems in LDCs must be undertaken (Falconi, 1999; RAFI, 1998).

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[2] The World Bank (1998) reports that the gap between developed and developing countries in knowledge capacity exceeds even the income gap.

Accordingly, the currently commercialised production trait GM crops contravene the belief system of social development organisations because they are being developed by MNC's driven by the profit motive with little regard for the socio-economic need of the developing country farmers who may be displaced by the technology. Hence, social development organisations support regulatory development and integration policies built on moral, ethical and/or religious preferences.

Notable social development organisations in opposition to GM crops include:

- Council for Responsible Genetics (US): focus on bioethics, distributes GeneWatch newsletter
- Joint Centre on International and Public Affairs and International Centre for Law and Development (US): focus on socio-economic issues
- Foundation for Economic Trends (US)
- Gen-Ethic Network (Germany): focus on bioethics and an informed public debate
- Christian Aid (International)
- World Development Movement
- Rural Advancement Fund International (RAFI)
- Canadian Institute for Environmental Law and Policy
- Third World Network
- Edmonds Institute
- Latin American Consortium on Agroecology and Development

4.2 Social Integration: A Case Study of the Biosafety Protocol

The Biosafety Protocol represents an international multilateral environmental agreement on the transboundary movement of biotechnology in pursuit of deeper social integration. It is important to assess for several reasons. First, the protocol is widely supported by social interests because it is based on the social rationality approach. Second, the EU has stated that rules and guidelines established under the protocol will be the foundation of the EU regulatory integration strategy dealing with biotechnology products (AgraFood Biotech No. 19, 1999). Hence, it is a proxy for the EU's trade policy position on GM crops. Third, it effectively illustrates the conflict between trade-oriented economic integration and deeper, social integration.

The UNEP was established in 1972 by the General Assembly as the UN's official environmental agency. Its mandate was to safeguard and enhance the environment for present and future generations. In other words, the mandate of UNEP was of sustainable development. The UNEP is involved in both technical scientific research on the environment and in reconciling the global objectives of environmental protection with other objectives, such as trade and economic development. For instance, the UNEP is involved in negotiations to establish international environmental law through multilateral environmental agreements (MEAs) such as the Montreal Protocol, the Basle Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and the Convention on Biodiversity (CBD).

Perhaps the most ambitious initiative of the UNEP is the Convention on Biodiversity and the subsequent negotiations to create a Biosafety Protocol (BSP). The BSP negotiations were an international effort, under the auspices of UNEP's 1992 Convention on Biodiversity (CBD). The CBD was the culmination of a decade-long effort, begun at the Third World Congress on National Parks and Protected Areas in Bali, Indonesia in 1982 (Swanson, 1997). The objective of the CBD was to develop an international convention to commit the global community to conserve and protect biodiversity. In June 1992 the CBD was included as Agenda 21 of the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, the Earth Summit, and was signed by participating countries at the Conference. The Biosafety Protocol (BSP) represents a proposed initiative to regulate the transboundary movement of living products of modern biotechnology in order to protect biodiversity. Negotiations concluded in January 2000 after being suspended in February 1999 because of significant obstacles. Essentially, the obstacles to the BSP are associated with the conflict between social interests supporting environmental objectives and economic interests supporting trade objectives; the BSP is driven from the environmental side, yet has significant potential trade implications.

In order to protect biodiversity, the initial scope of the BSP, according to the CBD, was to develop legally binding international rules governing the testing, importation and exportation (transboundary movement), deliberate release and commercial use of living modified organisms (LMOs). Specifically, the Advance Informed Agreement (AIA) principle was to be applied to shipments. This meant that the Party of Import would be notified prior to a shipment of LMOs. Further, the

LMOs would be subject to a risk assessment conducted by the Party of Import, in order to identify any potential risk(s) to the biodiversity of the importing region. The Party of Import, upon completion of the risk assessment, could allow or restrict the importation of the LMO because of identified risk(s) to biodiversity.

Although the BSP is not explicitly intended to be a trade agreement, the fact that its scope includes export and import activities makes it an implicit or de facto trade agreement associated with the international trade of GM products. A successful protocol has the potential to positively influence international trade in three significant ways. First through increased trade transparency according to the use of the AIA principle. Second through increased trade fairness because the risk assessment procedures are intended to ensure that biodiversity risks from GM products, whether domestic or foreign, are assessed consistently using credible procedures. Third, an international protocol could overcome the lack of domestic regulations in those countries with little or no experience with regulating GM products (Mulongoy, 1997). In this sense, the successful negotiation of the BSP can be interpreted as a potential win-win outcome. The global benefit, shared by all countries, is the overall conservation and protection of biodiversity. From an industry perspective, successful completion of the BSP has potential benefits for the further research, development, adoption and commercial use of GM products because it would potentially increase predictability and market access opportunities.

The administrative centre for the BSP negotiations, the seat of the CBD Secretariat, is in Montreal, Canada. There are over 120 countries involved in the BSP negotiations. There have been seven negotiating sessions completed to date: July 1996, Aarhus, Denmark; May 1997, Montreal, Canada; October 1997, Montreal, Canada; February 1998, Montreal, Canada; August 1998, Montreal, Canada; February 1999 at Cartegena, Columbia (suspended talks); and January 2000, Montreal, Canada.

The negotiations began with the discussion of general issues, including who should be involved in the negotiating sessions [i.e. signatories, industry representatives, environmental non-governmental organisations (ENGOs)] and with a request for draft protocol submissions by October 1996. Ethiopia submitted a draft protocol on behalf of the African delegation and the Third World Network (TWN) in October 1996. This draft protocol, considered as representative of the views of many developing countries, used as a framework the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (McDonald,

1997). As a result, the draft protocol treated shipments of LMOs with the same degree of prescriptive regulation as shipments of toxic or nuclear waste. Further, this draft protocol placed enormous burden upon the Party of Export and the exporter to ensure biosafety and to gain approval before any shipment of LMOs.

In response to the draft protocol submissions, the second negotiating session involved parties staking out their positions. The third session in October 1997 was characterised by the emerging awareness of the agricultural commodity trade issue and the potential impact of the protocol upon the international trade of products of modern biotechnology. Agricultural export countries reacted negatively to the Ethiopian draft protocol, highlighting the substantial differences of opinion between many developed and developing countries on what constitutes LMOs and their risks. The fourth and fifth sessions primarily involved the edification of crucial definitions and issues including the definition of LMOs, the roles of the Party of Export, the exporter, the importer and the Party of Import, the opportunity for exemptions, and the scope of the AIA. Many of these issues remain unresolved.

The sixth negotiating session was to be followed by the Extraordinary Conference of the Parties to the Convention (ECOP) where the final draft BSP was to presented for signing. However, on 24 February 1999, after it became clear that a final draft protocol was not going to be established, the decision was taken to push back the deadline for the final protocol for 18 months. The impasse emerged when the Miami group of countries (Canada, Australia, Argentina, Chile and Uruguay) rejected European efforts, supported by the other 140 negotiating countries, to extend the coverage of the Protocol to include risks to human health and to agri-food shipments intended for processing.

The seventh negotiating session, 24-28 January 2000 in Montreal, Canada resulting in the signing, by 140 countries, of the Montreal Protocol on Biosafety. The protocol distinguishes between LMOs intended for environmental release and GM commodities not intended for environmental release. The former are subject to an AIA for the first-time shipment only. While the latter are not subject to an AIA, but require mandatory labelling of GM material for the consumers' right know. The labelling rules are provisional pending further negotiations. The protocol also specifies that there must be a clear scientific justification to ban either LMOs or AIA, however, it also allows a 'precautionary' ban reflecting an environmental-type social

interpretation of the precautionary principle that can include socio-economic risks such as impacts on local farmers (to be discussed in greater detail in Chapter 5.2.1).

With respect to the prospects for international regulatory integration, the BSP is intended to be one international regulatory approach to the protection of biodiversity within a package of international environmental regulations included in the CBD, Agenda 21 as well as other UNEP activities. Indeed, attempts have been made, by developing countries to link the BSP to other international environmental regulations including the UNEP International Technical Guidelines for Safety in Biotechnology, which are guidelines for the development of domestic regulations that deal with the safe handling and containment of GMOs within a country, and the UN Recommendations on the Transport of Dangerous Goods, which are recommendations for the development of domestic regulations pertaining to the transport of hazardous and toxic materials. Notable by its absence is any effort to link the potential BSP with international trade agreements.

As it currently stands, the BSP is an environmental protection agreement dominated by the environmental social rationality ethos. It does have significant potential benefits for the transparency and fairness of the international trade of GM crops. Further, it is fundamentally congruent with the broader socio-economic concerns that the WTO framework fails to address and it favours a social interpretation of the precautionary principle. The BSP is based on consensus and the integration strategy of ex ante regulatory co-ordination. The proposed regulatory approach includes new horizontal and technology-based regulation for all products of modern biotechnology.

From the economic perspective, there are several important limitations to the BSP. First, unlike the IPPC there is no link to any international trade agreements, even though it is a de facto trade agreement, and there is no institutional mechanism for dispute settlement. Second, the US is not a signatory. Although not an official negotiating party (the US Congress has not ratified the 1992 CBD) the US remains the world leader in biotechnology research and plays an influential role in the negotiations. Whether the US position assumes a cautionary approach to the agricultural trade issue or an outright opposition to the BSP can have vital influence on those negotiating parties to the protocol which rely heavily upon market access to the US, such as Canada. Third, it will be at least 7 years before the BSP is in effect. Negotiations on the provisional labelling rules continue until 2002 while those for the

provisional liability laws continue until 2004. Once settled, the BSP must be ratified by at least 50 signatories and then transposed into national laws. Yet, during this time, technological innovation in agricultural biotechnology will continue, perhaps making the BSP obsolete as an international regulatory development and integration agreement.

Therefore, it appears that the BSP came about more as a political compromise than as an actual attempt to establish an institutional structure for GM crop regulations. The most contentious issues remain 'provisional' (unresolved) and the time-consuming ratification and implementation process could ensure its obsolescence. Its major contribution was the illusion that an international agreement blending the scientific and social rationality approaches and the economic and social perspectives had been achieved.

4.3 Conclusions

From a policy perspective, social interest organisations play a vital role in finding the regulatory middle as their extreme concerns counteract the extreme global welfare promises of the Life Sciences companies.

In general, most of the social interest organisations are dissatisfied with GM crops because they contravene a particular belief system. It is reasonable to suggest that most of the opposition to GM crops is the result of how the technology has been applied, by whom and for whom, providing a foothold for vast coalition of special interests. Indeed, an interesting aspect of the European anti-GM campaign is that while GM crops are not commercially grown in Europe, environmentally unsustainable agricultural practices supported by the CAP, which account for over 95% of EU production, continue without the concerted negative campaign targeted at GM crops. This is the case because GM crops provide a convergence of fear of the unknown associated with their credence factors and a perception of an invasion of foreign technology. Greenpeace, Friends of the Earth, etc. would be unable to generate as much public exposure and support if they were taking direct action against the commercial crops of European farmers, instead of the field trials of multinational (American) Life Sciences firms.

In some cases the normative beliefs are so strong that the organisations simply won't compromise and may be willing to take illegal action. Consider, for instance, environmental organisations. There has always been a minority element of eco-

warriors whose extremism was not supported by all, and could often be linked to a more holistic rejection of capitalism, technology and modern society. However, in the case of GM crops, illegal action has shifted to more mainstream organisations. For instance, in the UK in 1998, field trials of GM crops were destroyed by the more extreme group Gentix Snowball. By 1999, Friends of the Earth and Greenpeace were involved. The Director of Greenpeace UK, Lord Melchett, justified the illegal action by essentially claiming that ten years of legal protests did not result in regulatory policies adopting Greenpeace's belief system. This is a dangerous challenge to pluralism, which necessarily demands compromise and concession. It sets a dangerous precedent to justify illegal action because of the dissatisfaction that normative beliefs are not met in their entirety in the regulatory system. An example of the unwillingness or inability of Greenpeace to compromise was revealed in late 1999 at the Greenpeace Business Conference in London. Lord Melchett issued a challenge to the then Chairman and CEO of Monsanto, Bob Shapiro:

> *If Monsanto will stop developing GM crops, get out of producing pesticides and reject the idea of patenting life forms, Greenpeace will work enthusiastically with you...to produce a new Monsanto...We could create a genuine life sciences company based on ecological, organic, holistic principles (Greenpeace, 1999).*

In essence, this challenge is akin to asking Greenpeace to stop environmental advocacy.

Moreover, it is also reasonable to suggest that social interest organisations pursue their own self-interest in a manner which cannot be disentangled from the self-interest pursued by GM crop developers. Social interest organisations, such as Greenpeace, require membership to survive[3]. In this sense, many of the organisations are in competition with one another for members. Championing emotive issues through dramatic campaigns, or "picking good fights"(Bode, 1998) is an important method for sustaining public awareness of the organisations. Given the range of consumer concerns and the large (and growing) information gap between producers and consumers, there can be no doubt that GM crops is a good fight to pick because

[3] It has been noted that in 1991 Greenpeace's membership was 4.8 million and in 1999 it had fallen to 2.5 million [Economist (1 August 1998) Vol. 348, No. 8079, p. 76]. The same article also notes that Greenpeace has considered the development of a Greenpeace Eco-label.

they can easily be inaccurately portrayed, in order to develop particularly emotive issues.

This raises three important questions. First, despite the very public opposition to GM crops by many social organisations, do they really have significant regulatory and trade policy power? The answer is yes, and policy-makers ignore them at their peril. In the UK, Monsanto has admitted that the anti-GM campaign, which has been portrayed as an anti-Monsanto campaign, has been damaging to its business reputation and its share price (Independent, 5 September 1999). As a result, the Monsanto President and Chairman made efforts to establish a dialogue with the anti-GM campaigners. The interesting problem will be the willingness and ability of the organisations to compromise their belief systems. Have they created such a public resistance, that when they realise there are benefits from GM crops they will be unable to compromise? Suppose this were the case, it makes a strong argument for why regulatory development should be science-based and rules-based, rather than a knee-jerk approach to assuaging unsubstantiated concerns and non-substantiated risks.

Second, what would have happened if the first GM crops were developed by supporters of organic farming in a public research institute designed to employ the technology to assist the sustainable development needs of less developed countries, rather than by MNCs targeting intensive agricultural farmers in developed countries? It is a question worth considering. Given the application focus of these interests, it is reasonable to argue that, indeed, if the initial commercialisations were different so too would be the reaction of many of the current opponents. Further, given that most of these social interest organisations would like to see the establishment of a strong international institution with as much, if not more power than the WTO to enforce the social rationality approach, it can hardly be said that they are anti-globalisation as well.

Third, although there has been a considerable range of civil society organisations united in opposition to GM crops, is this unity of opposition to GM crops sustainable in the medium- to long-term? For instance, consumer organisations are in support of higher domestic food safety and environmental protection standards. Social development organisations want better access to developed markets for LDC exports. Yet, setting income elastic food safety and environmental protection standards in developed markets could prohibitively bar the exports of LDCs. The

incompatibility of all of these organisations lends credence to the argument that they have chosen GM crops because of its easily exploitable emotive characteristics.

In summary, the examination of the opposition to GM crops from consumer, environmental and social development organisations reveals several interesting results. First, it is not the GM crops per se that are the source of dissatisfaction. Rather, they are rejected because the initially commercialised applications are produced for an agronomic system and by multinational corporations who play by the WTO's trade rules that contravene the belief systems of the social interests organisations. Second, the opposition to GM crops is formidable and neither government regulators nor industry can ignore it. Third, the current unity of opposition to GM crops is not sustainable as the various organisations are in pursuit of incompatible objectives. Fourth, it appears that the opposition to GM crops resulting in calls for greater regulatory oversight and weaker intellectual property protection are, in fact, having the effect of increasing the concentration of agricultural Life Science firms. That is, multinational firms are forced into greater concentration in order to deal with the affects of stringent regulatory oversight and unclear intellectual property protection rules.

This examination of social interests reveals that regulatory policy must be sensitive to two social parameters. First, is must focus on the application, management and distribution concerns of the social interest organisations. Second, regulatory development cannot ignore the criticisms of social interest groups. They must have a policy voice.

CHAPTER FIVE REGULATORY DEVELOPMENT AND INTEGRATION

The discussion of the economic and social interests reveals that they support very divergent approaches to regulatory development and regulatory integration and that establishing a regulatory development and integration approach must be understood as a political exercise of balancing technological progress with technological precaution. Given the general discussion of the economic and social interests, it is now possible to analyse the development of GM crop regulations in order to identify the sources of regulatory instability and the limitations of the traditional trade approach to regulatory integration.

5.1 Regulating Technology: The Risk Analysis Framework

At the core of the debates on regulating GM crops is the broader issue of regulating technology. It is a challenging public policy problem because technological innovation, while promising opportunity, has always encountered public anxiety about its risks. Such anxiety has always been associated with agricultural innovations:

> *We have already advanced our knowledge of genetics to the point where we can manipulate life in a way never intended by nature. We must proceed with utmost caution in the application of this new found knowledge (Burbank, 1906 in Bruhn, 1993).*

This quote captures many of the current concerns about GM crops. It was written, however, in 1906 and it refers to the techniques of traditional plant breeding. Therefore, the techniques, which many now consider as the 'safe old methods', were met with anxiety and hostility similar to that currently facing GM crops.

Technological innovation is a dynamic process where research and development builds both capacity and the knowledge base, which in turn increases the potential for further innovations and for specific commercial applications. Yet, this simultaneously increases the information gap between producers and consumers and exacerbates the credence nature of advanced technology products such as GM crops. The increasing sophistication and credence nature of the technology decreases the ability of consumers to understand the actual risks and to act rationally on their own. Instead, consumers must rely upon others, such as industry, government regulators or a third-party, to address the credence concerns on their behalf.

In this sense, the development of regulations to deal with GM crop technologies must focus on two broad objectives. First, regulation must strike a political balance between technological progress and technological precaution. There is no such thing as certainty in either the opportunities or the risks of new technologies and it is the acceptability of the relative trade-off between the risks and opportunities of a new technology that matters. Regulations cannot be expected to build consensus among normative views on technology (van den Daele *et al.*, 1997). Uncertainty, risk and divergent normative views, as with all things, are an inherent part of GM crops, and the best that regulatory approaches can hope to achieve is a socially acceptable balance, not a risk free balance. Second, regulations must be dynamic and capable of keeping pace with the commercial applications of new technologies. This means that as GM crop applications deepen and widen regulation must consider the regulatory issues that arise from new production and output improved GM crops and from novel Bio-Engineered products. This puts pressure on the limited resources of government regulators implying that regulatory resources must be strategically targeted. For instance, it has been argued that the regulatory goal should not be to develop a comprehensive regulatory approach of complete command and control because it will quickly become obsolete. Instead, the goal should be to develop a dynamic management approach capable of steering "the matured technology in beneficial directions"(Fincham and Ravetz, 1991).

Risk Analysis is widely considered by both economic and social interests to be an effective framework for simultaneously addressing both the complexities and the limitations facing regulatory development as a result of sophisticated technologies such as GM crops. The Risk Analysis framework was first outlined in 1983 by the Redbook of the US National Academy of Sciences (NAS, 1983). According to this publication, Risk Analysis is composed of three parts; risk assessment, risk management and risk communication.

Risk assessment has the goal of, to the extent possible, developing objective, neutral, transparent and consensual information about the risks without normative influence. Risk assessment involves hazard identification, exposure assessment and risk characterisation according to a sound scientific basis using accepted analytical methods and statistical inference techniques. The information gathered in the risk assessment stage, is then used to inform the risk management process.

The goal of risk management is risk prevention and risk reduction. This involves incorporating the objective risk information into a regulatory response. As risk management is where the regulatory position is adopted, this stage must also address the broader economic, political, social, moral and ethical factors beyond a scientific basis. In this sense, risk management explicitly requires compromise and concession as it balances the rights and interests of all stakeholders in order to establish an acceptable regulatory framework.

The Redbook specified that risk assessment techniques should be institutionally separated from risk management procedures. Essentially, it is vital to disentangle the objective, scientific risk assessment from the normative public response to risk.

Risk communication is a two-way flow of information between risk assessment and risk management as well as between regulators, industry and the public. While the scientific risk assessment information must flow to the regulatory development process in risk management, it is also necessary for the social parameters of risk management to flow back into the risk assessment techniques (MacKenzie, 1993). As was shown in Chapter 2, there has been a failure of risk communication with respect to GM crops. Much of the information provided to consumers has been either the industry's *global welfare promise* or from the highly critical environmental lobby. Such a polarity of information has left many consumers confused and given their propensity to trust third-party non-governmental organisations, many consumers have an unsubstantiated negative perception of GM crops. In this sense, the goals of risk communication would be to reduce the credence factors and the information gap and to increase confidence in the regulatory framework through greater transparency.

A vital contribution of the Redbook's Risk Analysis framework was the integration of scientific analytical procedures into the regulatory development process. There are two important reasons why science matters. First, scientific analysis has long strove to disentangle normative values from scientific discovery. Although a complete separation has, and will never occur there is a level of universality to 'science' that is not present in social beliefs, morals and ethics. As regulations apply across a wide range of social beliefs, morals and ethics, they should endeavour to be as normative-free as possible. For instance, food safety regulations should be focused on human safety, equally applicable to all citizens, and not on regulations that support the social values of some, while contravening the values of others.

Second, while scientific disagreement can, and does frequently occur, the analytical methodology of science permits debate on disagreement subject to relatively accepted rules of evidence[1], unlike normative disagreements which, based on beliefs, have no apparent methodology or process for resolution. The Risk Analysis framework seeks to establish a sound scientific basis for risk assessment in order to develop, as much as possible, neutral and objective information to advise the risk management process, while risk communication is intended to provide transparency to the entire regulatory development process.

Despite the widespread support for the Risk Analysis framework, there are seven general or framework debates representing a conflict between the Risk Analysis framework supported by economic interests and that supported by social interests. Within the context of these framework debates on regulating technology are five specific debates on GM crop regulatory principles, which are examined after the general debates. It will be shown that GM crops regulations are unstable as they shift within the Risk Analysis parameters according to the competing influence of economic and social interests. As these debates fundamentally influence the path of regulatory development within a jurisdiction and the prospects for regulatory integration between jurisdictions, it is crucial to examine each one.

5.1.1 Scientific Rationality v. Social Rationality in Risk Assessment

Often Risk Analysis, especially the risk assessment procedure, is portrayed as an approach congruent with the scientific rationality paradigm and incongruent with the social rationality paradigm. This debate is at the heart of the conflict between the economic and the social interests identified in the previous two chapters. It is now possible to define these concepts in a regulatory context.

According to the scientific rationality or traditional rational thought perspective it is possible to derive scientific facts that are universal and that lead to certainty. In one approach, it has been argued that researchers can ask either scientific empirical questions or social normative questions (van den Daele *et al.*, 1997). Empirical questions can be assessed according to accepted analytical methods with specified causal-consequence mechanisms to show risk. Such questions for GM crops would include does a risk exist? and how likely is it to happen? Empirical questions

[1] See Chapter 7 for an illustrative example of how scientific rationality dealt with disagreement in the case of Dr. Pustzai.

produce 'matters of knowledge' which can be based on consensus while normative questions involve consideration of different systems of belief not based on any analytical method. Social normative questions for GM crops would include is the risk acceptable? These questions are not prone to consensus and there is no obvious method for resolving conflicts among belief systems. In comparing the two, scientific rationality posits that empirical questions are logically prior to normative questions, hence, empirical questions can produce neutral, objective and universal facts that should be the basis of risk assessment procedures.

On the other hand, the social rationality paradigm rejects the idea of universal facts. Instead, empirical questions and answers are considered to be scientific myths because facts cannot exist without value and social dimensions cannot be separated from science. The social rationality paradigm suggests that neutral and objective risk assessment is a flawed concept. It challenges the scientific Risk Analysis framework as an effective framework for developing regulations for new technologies (see Grove-White *et al.*, 1997) because the scientific Risk Analysis framework fails to address the complex interactions between technology and society (Grove-White, 1997; Sheppard, 1997; Giddons, 1994).

This debate represents a fundamental conflict in regulatory development and integration, and it is the basis for the remaining framework debates on the role of science in GM crop regulations. Economic interests view scientific risk assessment as a means for disentangling actual risk from perceived risk and normative social preferences. It is held that empirical analysis according to accepted methods and causal-consequence models provide a degree of universality to risk assessments of GM crops providing a certain, rules-based foundation for regulations. Social interests view social risk assessment as a necessary requirement for establishing socially responsive regulations. In this sense, they do not distinguish between actual and perceived risk because perceived risk is held as an equally legitimate trigger for regulatory change and development. Given this difference it is vital to recognise the influence of the economic and social interests within the regulatory development process of a jurisdiction as will be done in Chapters 6 and 7.

5.1.2 Type of 'Risk' Targeted in Risk Assessment

Another important debate associated with the Risk Analysis framework involves the type of risk targeted where three types may be identified: recognisable

risks, hypothetical risks and speculative risks (van den Daele *et al.*, 1997). Recognisable risks can be identified through experience (data) and the application of accepted analytical methods such as statistical inference and probability theory, and they include a clear causal-consequence mechanism. Hypothetical risks lack experience or data, but, with the help of assumptions and/or likelihood functions they can be assessed within an accepted analytical method. Speculative risks lack experience, data, a causal-consequence mechanism and an accepted analytical method for assessment. They are logical possibilities; irrefutable, but untestable as well[2].

An added dimension to the type of risk is the risk consequence. There are two types of consequences; dread and diffuse. Dread consequences are sudden and catastrophic while diffuse consequences are long-run and cumulative but not catastrophic. It has been argued that dread consequences have important implications on risk-related behaviour. They can upwardly bias the perception of both consumers and regulators about possible recurrence (Camerer and Kunreuther, 1989). And, they can create ambiguity-averse behaviour where consumers and regulators over-estimate the risk of products because of the credence factors (MacLaren, 1997). For example, it appears that the French decision in 1999 not to lift the ban on British beef is a combination of speculative risks and dread consequences. Further, this 'fear factor' spread to both Germany and the European Commission who wanted to review the French scientific risk assessment before making any further decisions on the beef ban (Times, 9 October 1999).

New technology always faces either hypothetical or speculative risks because by definition there is no experience or data about the risks. The controversy arises over the extent to which GM crops should be assessed according to hypothetical or speculative risks. Many supporters of a social rationality paradigm have made dire predictions of 'genetic pollution' and ecological disaster because of the use of GM crops (Rifkin, 1998; Ho, 1998). They appear to focus on speculative risks and argue on the basis of logical possibilities targeted to public concerns about the credence factors of GM crops and alluding to dread consequences. Due to these speculative risks, which cannot be refuted, they claim that scientific Risk Analysis is an

[2] For examples of statements of speculative risks of GM crops see: Sheppard (1997a,b); Consumers' Association (1997); The Ecologist (1998). Although only a brief list, these references clearly indicate the widespread use of speculative risks with respect to GM crops. In each, no recognisable or hypothetical risks are proposed. Instead, they all refer to dread consequences of GM crops based on speculative risks.

insufficient framework and without a sufficient regulatory approach GM crops must be banned[3].

Supporters of the scientific rationality approach tend to argue, however, that the problem is not with Risk Analysis, but with the deliberately vague nature of speculative risks (Fincham and Ravetz, 1991; van den Daele *et al.*, 1997). They agree that speculative risks cannot be proven wrong as "it is scientifically impossible to prove the impossibility of an unwanted event; and this may seem to be what is demanded by protesters" (Fincham and Ravetz, 1991). However, they counter that speculative risks cannot be proven right either. Regulatory risk assessment can only address a finite set of risks, but there are infinite logical possibilities. Speculative risks are the safe-harbour for those uninterested in a genuine dialogue about new technology and are inappropriate because regulations are about balancing the rights and interests of supporters and critics requiring dialogue, debate and compromise.

A social rationality regulatory approach targeting speculative risks would result in no new technology ever being approved because speculative risks can always be found. Yet, an infinite number of speculative risks can also be identified for previously approved old technologies such as traditional plant breeding techniques. So must they too be rejected? Of course, they wouldn't be because, due to experience and data, they are now associated with recognisable risks. Banning a technology because of speculative risks prohibits the shift from hypothetical to recognisable risks. Scientific rationality posits that speculative risk assessments are not an acceptable basis for regulatory development and instead hypothetical risk assessments must be the basis for managing the application and distribution of new technologies.

5.1.3 Substantial Equivalence in Risk Assessment

The regulatory equivalence of GM and non-GM crops is a very significant controversy associated with GM crop regulations based on the Risk Analysis framework. Substantial equivalence is a regulatory principle implying that regardless of the differences in the process and production methods the risks from a product are substantially equivalent to the risks from another 'like' product. It is important to note that substantial equivalence does not imply that GM crops and GM foods are risk free. Realistically there are risks that cannot be denied. But, crucially, substantial

[3] Also NCC (1998) defines hypothetical risk as 'risk' and speculative risk as 'true uncertainty' and then argues that risk assessment is problematic because it does not take account of 'true uncertainty'.

equivalence simply means that the risks are not greater than those risks from other like products, such as from traditionally bred agricultural crops planted and consumed for thousands of years.

Social interests tend to claim that GM crops are not substantially equivalent to non-GM crops because it is the use of modern biotechnology, especially transgenic modification across the species barriers that changes the fundamental nature of GM crops and incurs special risks not evidenced in conventional plant breeding.

On the other hand, economic interests, supporting scientific rationality, claim that the key issue is not the application of modern biotechnology per se, but the novelty of the resultant crop (see Chapter 2.1.1 for a discussion of novelty). They argue that transgenic modification techniques are simply more precise and sophisticated plant breeding techniques, so-called 'modern plant breeding' (Economist, 25 July 1998). In support of this view, the UN's World Health Organization published a report on the principle of substantial equivalence in safety evaluations of food products derived from GM crops (WHO, 1995). This report concluded that GM crops may be substantially equivalent to non-GM crops for risk assessment purposes and that novelty was the justification for new regulatory oversight, not the use of genetic modification per se. According to this perspective, most production trait GM crops and some output trait GM crops are substantially equivalent but Bio-Engineered products will not be substantially equivalent because they are, by definition, all novel. Substantial equivalence is a well-established principle in international regulations supported by institutions such as the WHO, the FAO, the OECD, the Codex and the IPPC.

Substantial equivalence may be assessed over both scientific factors (van den Daele *et al.*, 1997) and normative factors (Nuffield Institute, 1999). Two popular arguments in support of the social rationality assertion that GM crops are not substantially equivalent are (1) that it is wrong to engineer living things and (2) that it is wrong to transfer genes between species[4]. With respect to the first argument, the notion of engineering plants cannot be limited to GM crops only. To reject GM crops on the basis that they are engineered, requires a rejection of all agricultural crops, including organic varieties, because it is impossible to disentangle the engineering of GM crops from the engineering of non-GM agricultural crops (Nuffield Institute,

[4] These are bio-centric ethical or moral arguments based on the idea that nature has boundaries and it is not right for humans to be tampering with those boundaries.

1999). Consider that GM crops are modified varieties of conventional crops already engineered and made unnatural by generations of traditional plant breeding. Similar to all conventional crops, GM crops have been developed to fit within an 'unnatural' agricultural production system, not to grow in the wild, and to express desirable traits for human use, where these traits are not designed to confer any natural advantage to these crops relative to wild plants. It has been noted that "by itself genetic modification does not normally confer qualities that will make an organism more harmful to mankind or the environment" (Fincham and Ravetz, 1991). In other words, to argue that it is wrong to engineer living things and reject GM crops on this basis requires a similar rejection of all agricultural crops that also have been engineered to grow in an unnatural, man-made environment in order to meet human needs.

With respect to the second argument, from a scientific perspective, gene transfer and modification even across the species barrier is a naturally occurring phenomenon not specific to transgenic modification techniques[5]. Indeed, genetic drift has always occurred between non-GM crops, wild relatives, other vegetation and soil micro-organisms. In fact, it may be argued that GM crops involve more precise and specific modifications that are specifically monitored rather than the unmonitored random type that naturally occur, conferring much greater control to the plant breeder than previously possible.

Examining the scientific and normative factors tends to support the substantial equivalence of GM and non-GM crops for risk assessment procedures. Given this substantial equivalence, it is not a legitimate argument to reject GM crops because they are harmful to biodiversity (van den Daele *et al.*, 1997). By definition, all agricultural production is harmful to biodiversity. It must be accepted that production takes priority over biodiversity on agricultural land. The objective, given the priority of production, must be to minimise the impact of agricultural production upon biodiversity and there is no reason why GM crops cannot assist in minimising the impact.

Hence, from a regulatory perspective, the key issue is not the transgenic modification per se, but the 'artificialness' of the modification, such as the transfer of the anti-freeze gene of arctic fish into crops to protect them from freezing. This is an application-specific concern focused on novelty, not a process-based concern

[5] Ho (1998) notes that viruses have the natural ability to transfer genes between unrelated/sexually incompatible species, therefore, transgenic modification cannot be seen as unnatural.

associated with transgenic modification. This implies that for risk assessment procedures, some GM crops are substantially equivalent provided they are not novel.

An important example of the debate over substantial equivalence concerns the relationship between GM crops and organic crop varieties. A common position is that organic produce provides consumers with a GM-free alternative. However, the debate arises because many seed developers reject the notion that GM seeds cannot be used in an organic production system. They argue that organic refers to a more labour-intensive production process, eliminating the use of artificial fertilisers, chemicals and pesticide residues replacing them with a more integrated crop rotation and pest and weed management system. In this sense, organic is about the production method, and GM crops developed to be congruent with such a production method are substantially equivalent to conventional organic varieties. Critics of the substantial equivalence principle argue that it is the use of GM techniques which fundamentally changes the nature of GM crops and makes them incompatible with organic systems.

5.1.4 Science v. Other Legitimate Factors in Risk Assessment

Within the context of risk assessment, there is debate over whether risk should only relate to science-based, empirical definitions of safety or to broader socio-economic factors. From a food safety perspective, there are four different regulatory targets or hurdles that may be employed in assessing the 'risk' or safety of foods derived from GM crops. The first target is food safety defined as the absence of short-term illness immediately after consumption; the classic food poisoning case. The second target is long-term human health such as the cumulative impacts of consumption over time. The third target involves assessing the quality or efficacy of the food product relative to other products in the same-use category. The fourth target includes assessments of the broader socio-economic impacts of the use of GM foods in the food supply. This includes, for instance, assessing the 'risks' of GM crop production upon the welfare of farmers who produce them and upon those who produce complements or alternatives. For example, in the fall of 1999 Thailand imposed a provisional import ban on GM material pending proof of its social benefit, not just its safety. It was argued by Thailand's International Economic Relations Policy Committee that imports should not resume "until the public accepts that GM food provides more benefits than drawbacks" (World Food Law Monthly No. 19, 1999).

Most foods are analysed according to the first target; a scientific assessment of their potential to cause short-term illness only. Fast foods and junk foods with recognisable risks of severe long-term health implications are approved as safe and are widely available in the marketplace. In approving such foods, little consideration is given to long-term health consequences and to food quality and none is given to the socio-economic impacts upon, for example, the health care system or worker absenteeism because of chronically unfit consumers.

Social rationality supporters generally argue that GM crops should be assessed according to all four targets or regulatory hurdles. Scientific rationality supporters dispute this argument for three reasons. First, it is inconsistent with the traditional science-based approach to food safety assessments. The 1995 amendments to the Codex procedural manual supported only the first regulatory hurdle (CAC, 1995; see also Chapter 3.2.1.C). Second, there is no justification for assessing GM crops any differently than conventional crops in the food supply because of their substantial equivalence. Third, even hypothetical risks associated with the safety of foods from GM crops have not been shown. In fact, a paradoxical development in the UK is the removal of GM ingredients from the products of the top ten fast food restaurant chains. No hypothetical risks to human safety and health have been shown from GM crops, yet there is considerable information on the recognisable risks from fast food. This development is simply not about food safety.

Similarly, hypothetical risks to environmental biodiversity from GM crops may be analysed according to an empirical scientific assessment or according to a broader socio-economic assessment of other legitimate factors. For instance, the UK Economic and Social Research Council argued:

> *Current approaches to environmental risk assessment exclude wider dimensions of risk, such as justification, need, benefit, the context of use, and public confidence in the trust worthiness of regulatory provisions and institutions themselves...the mechanisms in question are not appropriate for addressing such issues adequately and there are no other fora for addressing these dimensions* (in Mayer *et al.*, 1996)[6].

[6] Also see Sheppard (1997a) who argues that "A re-evaluation of the risks, need and justification for GM foods, one that extends beyond what is normally thought of as 'risk assessment' is urgently required".

Again, this would include, for instance, an assessment of the impact of GM crop production upon the social welfare of other economic sectors both complementary to and competing with GM crops. The serious problem arises when a critic's dissatisfaction with 'need' and 'justification' is manifested through speculative, unsubstantiated and spurious warnings or dire predictions of the safety of GM crops.

In short, scientific rationality supports primarily the first hurdle for regulatory oversight while social rationality supports all four regulatory hurdles.

5.1.5 Burden of Proof in Risk Assessment

The traditional regulatory approach to new technology, supported by economic interests, generally reflects a scientific rationality approach where new technological innovations are innocent until proven guilty. That is, unless an innovation is proven to be harmful there is no justification for a restriction or a ban on the technology.

From a statistical probability theory perspective there are two types of risk or errors to consider. With respect to GM crops, Type I risk would be the risk that the crops are rejected as unsafe, when in fact they are safe. While Type II risk would be the risk that the crops are accepted as safe, when in fact they are unsafe. The controversy arises, because Type I and II risks cannot be simultaneously minimised, and, instead, if one type of risk or error is decreased, the other is increased (Greene 1997). The debate is how to decide between the two.

The traditional burden of proof minimises Type I risk (rejected when safe) and supporters argue that this paradigm has been proven effective at ensuring an acceptable level of relative safety of products while encouraging further innovation. Generally, this requires the assumption that firms actively minimise safety risks while pursuing innovation. It has been argued that firms are both able and willing to ensure both food and environmental safety because a crisis is a commercial disaster (Spriggs and Isaac, In Press). According to this view, despite claims of 'reductionist' science or captured scientists, the market is working in internalising the costs of risk because producers who minimise commercial risk are simultaneously minimising food and environmental safety risks. Indeed, an important aspect of ensuring that firms do internalise food and environmental safety risks as commercial risks is to have stringent product liability laws to compel the firms to ensure safety.

The traditional burden of proof has important commercial advantages. It enhances regulatory stability and certainty for firms encouraging the management of

product applications of new technologies. This allows for hypothetical risks to begin to move towards recognisable risks, increasing regulatory experience and decreasing the time and costs required for regulatory oversight. Ultimately increasing the competitiveness of the advanced technology firms (Lavoie and Sheldon, 1999). It is also argued that too much regulation is not optimal for technological innovation because it confers advantage to large established firms who have the resources to deal with complex regulations (Zilberman *et al.*, 1997). This decreases the diffusion of technology and decreases the number of potential commercial applications, which in turn decreases consumer choice. In other words, the social rationality approach, opposed to multinational Life Sciences firms may actually be supporting the competitive position of these firms by calling for greater regulatory oversight to meet public fears because only these firms have the resources necessary to deal with the complex regulations.

The social rationality approach to regulating new technologies tends to want the burden of proof reversed so that the focus of risk assessment is on minimising Type II risk (accepted when unsafe). In this case, GM crops and food produced from GM crops are assumed to be unsafe until they can be conclusively proven to be safe. In fact, some critics want the burden of proof not only reversed but also extended to include other legitimate factors as well. GM crops and GM foods would be rejected unless they could be proven safe and socially beneficial and hence, meet all four regulatory hurdles from 5.1.4 above.

It appears that the keys to this debate are the type of risk targeted and the principle of substantial equivalence. For instance, if the burden of proof is reversed and the critics were arguing from the perspective of speculative risks about non-equivalent GM crops, then GM crops would never be approved because there would be no way to disprove the logical possibility of Type II speculative risks. Further, there would be no accepted analytical methods for identifying and then minimising the speculative Type II risk. The implication is that regulatory responses would be biased against the techniques of modern biotechnologies and in favour of the more random, imprecise techniques of traditional plant breeding, even though traditionally bred crops are also associated with speculative risks.

Yet, reversing the burden of proof in risk assessment appears unnecessary if risk assessment is based on hypothetical risk and GM crops are substantially equivalent to the same use conventional crops. In this case, focusing on hypothetical

risks means that accepted analytical methods may be employed to identify and minimise Type I risks. There would be no scientific or empirical reason to shift from the minimisation of Type I risks to Type II risks because GM crops would be considered substantially equivalent.

5.1.6 Risk Tolerance in Risk Management

Once the risk assessment is complete, determining what level of risk is acceptable is a risk management procedure. The standard approach is to establish tolerance levels because zero risk is not possible. "The concept of zero risk to the consumer from the food supply although attractive and the ultimate aim of food safety, given the current level of knowledge is not a feasible option" (Majewski, 1997). Yet, despite this reality there have been pressures for zero tolerance risk management policies associated with GM crop regulations. The controversy arises because risk management must balance the economic interests of supporters who support a risk tolerance level for the presence of GM material in food products, with these social interests who demand zero risk.

Tolerance levels are established for the presence of many types of possible materials in food products such as the content of rat hair in macaroni, bugs in flour, or pesticide levels on vegetables[7]. Also, organic labelling policies also accept tolerance levels. For example, the EU organic labelling regulation (EC 2092/91) states that a food product must have at least 95% organic ingredients in order to be legitimately labelled as organic. Also, while some want zero tolerance policies on the presence of GM materials in food products, a specific level of pesticide residue is tolerated. Pesticide residues and GM material are conceptually similar in the sense that they are generally in food products without the consumer knowing, or at least being sure. Yet, there are important differences. First, GM crops have not been shown to have even hypothetical safety and health risks, while there is considerable information about the recognisable safety and health risks of pesticides. Second, while humans are designed to digest proteins, they are not designed to digest synthetic chemicals. Scientific rationality supporters would argue that it is an irrational result that synthetic chemicals with known recognisable risks are tolerated to a certain level, while protein-based

[7] See the Food and Drug Administration of the United States Department of Health and Human Services website on permissible food adulteration.

genetic modifications that have not been to shown to have even hypothetical risks to human safety and health are the target of zero tolerance pressures.

5.1.7 Science v. Other Legitimate Factors In Risk Management

According to the Risk Analysis framework, risk assessment must be free of normative considerations to the extent possible, while the risk management process is where the rights and interests of all stakeholders must be balanced. There are three debates associated with this.

The first controversy arises because, as was shown in Chapter 4, many of the critics base their rejection of GM crops upon a belief system that is not open to compromise or concession. For instance, rejection of GM crops because of moral, ethical or religious beliefs about genetic engineering are not usually open to compromise[8]. Another example is critics of GM crops who support organic farming. Such critics often reject GM crops because of their rejection of the broader paradigm of intensive agricultural production. Instead of comparing an insecticidal GM variety of corn to a non-GM variety in terms of the benefits accrued because of the reduction in pesticide used in an intensive system, they compare the GM variety to an organic variety in an organic system and conclude that GM varieties are just not good enough. The problem here is that supporters and critics are arguing from different frames of reference (van den Daele *et al.*, 1997) and it is difficult to achieve compromise between different frames of reference.

The second debate arises because some argue that risk management should be based on scientific risk assessment and it should remain as objective and neutral as possible, not a venue for political compromise and concession. According to this view, the objective of risk management is the reduction and prevention of scientifically determined risk and this can be achieved without normative influence or consideration of other legitimate factors. For instance, proposed US regulations are analysed by the Office of Management and Budget to ensure that they are capable of achieving desired outcomes and that they are not the product of political objectives (see Chapter 6). The risk management is expected to focus on the reduction and prevention of hypothetical risk, not on the assuaging of public fears and concerns about speculative risks.

[8] Akerlof, G. and W. Dickens (1982) argue that consumer beliefs persist over time and are difficult to change.

The third debate arises because if it is accepted that risk management is inherently a political function, then it must be performed by elected officials. Yet, it has been argued that consumers do not believe that elected officials can appropriately play this role (Grove-White *et al.*, 1997). If this is the case, then who should take the risk management decisions? The responsibility appears to slide back down to the scientific risk assessors (who must necessarily be free of normative factors in order to arrive at independent risk information), yet the public allegedly does not trust the scientists either. How can regulatory development escape this conundrum? It has been argued that non-governmental organisations can fill this role by acting as honest brokers in precautionary regulatory development (Grove-White *et al.*, 1997), however this results in the entirely unacceptable situation of an unaccountable third-party interest groups responsible for regulations.

5.2 Principles of GM Crop Regulations

The seven general debates associated with the Risk Analysis framework reveal the existence of a significant range of views on the appropriate way to regulate advanced technologies. This gives rise to a challenging exercise of compromise and concession in the regulatory development process in an effort to balance technological progress with precaution. This challenge is exacerbated, however, by the development and commercialisation of GM crops because there are five specific debates over the fundamental principles for regulating them.

The objective of this section is to identify the five specific regulatory debates. The key point is that while two jurisdictions may claim to have Risk Analysis-based regulations, the range of views and debates means that the approaches can, in fact, be significantly divergent.

5.2.1 The Precautionary Principle

Most countries claim to base their GM crop regulations on the precautionary principle. Yet, the use of the precautionary principle in GM crop regulations is associated with a significant degree of misunderstanding. In general, the precautionary principle implies that in the face of uncertainty regulators must over-estimate risk. However, in an operational sense the precautionary principle has two somewhat different interpretations and regulatory jurisdictions can employ either of the two interpretations. The first interpretation, supported by scientific rationality, considers it

to be a scientific risk assessment tool while the second, supported by social rationality, considers it to be a social risk management tool.

As a scientific risk assessment tool, the precautionary principle refers to the manner in which hypothetical risks are assessed. Recall that hypothetical risks are those that lack experience or data, but, with the help of assumptions and/or likelihood functions risks may be assessed within an accepted analytical method. Applying the precautionary principle at this stage would entail setting very risk averse assumptions or parameters in the likelihood functions to ensure that uncertainty is sufficiently dealt with. Then hypothetical risks are calculated by credible experts according to accepted analytical methods and according to the traditional burden of proof. The hypothetical risks are 'precautionary' because the precautionary principle has been built into the risk assessment process. This approach accepts that regulators can only be *reasonably certain* of no adverse affects. It still supports the research, development and commercialisation efforts that further the knowledge base and lead to greater understanding of the risks. Further, the hypothetical risk assessment information is then used to advise the risk management procedure.

As a social risk management tool, the precautionary principle is the vehicle for allowing speculative risks into the risk management procedure. Recall that speculative risks lack experience, data, a causal-consequence mechanism and an accepted analytical method for assessment. They are irrefutable logical possibilities where a scientific risk assessment cannot be performed. Instead, speculative risks are 'best guesses' introduced into the risk management procedure with no analytical or empirical method of evaluation.

The social interpretation has its roots in environmental literature (Tait and Levidow, 1992). The Rio Declaration stated that:

> *In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

The concern is that ecosystems are so poorly understood that precaution must be taken in approving the environmental release of products that may have irreversible or irreparable impacts. Anticipating the worst, regulators pursue zero risk in the sense

that under the precautionary principle they must be *certain* of no adverse affects. They heavily scrutinise research and development and do not permit commercialisation until it can be proven to be free of risk. Further, because the risk management procedure involves balancing the rights and interests of supporters and critics, many different actors can introduce speculative risks into the risk management procedure, which is unlike hypothetical risk assessment where the risk information is compiled by credible 'experts'.

Clearly, the interpretation of the precautionary principle employed can lead to significantly different regulatory outcomes. The scientific interpretation is favoured by international standards-setting institutions such as the Codex and the IPPC. The social interpretation has been established in the Biosafety Protocol and is supported by social interests groups (TACD, 1999b; Consumers' Association of Canada, 1994).

The dual interpretation of the precautionary principle has created the unusual situation in the Codex where Canada and the US claim that Codex does employ the precautionary principle while the EU claims that it does not. In fact, the dual interpretation can be expected to cause trade tensions. Consider, for instance, that IPPC employs the scientific interpretation in developing phyto-sanitary measures, yet the environmental tradition is to use the social interpretation. As Members enact phyto-sanitary measure against GM crops, these measures will be evaluated in terms of their scientific justifications. In this case, the TBT Committee or the WTO dispute settlement mechanism will be charged with making the unenviable decision on which interpretation of the precautionary principle is acceptable and which is not.

5.2.2 Regulatory Focus: Products v. Processes

Domestic regulations on biotechnology focus either on the products created through the use of biotechnology or on the processes (i.e. how the products are made). This is the so-called products v. processes debate.

Regulating products, not processes, is the traditional regulatory approach to regulating advanced technologies. Product-based regulations for GM crops and products derived from GM crops would be congruent with the traditional approach. This is the regulatory approach supported by economic interests focused on application-based, novelty regulations.

On the other hand, regulating according to the use of modern biotechnology, especially transgenic modification, is not congruent with the traditional approach.

Modern biotechnology is employed across many sectors, such as agriculture, forestry, fisheries, pharmaceuticals, medicine, and the environment. These sectors have been regulated independently, pursuant to specific, often divergent mandates. Regulating the process requires regulations applicable to all sectoral applications, despite the divergent mandates. Social interests regard this approach as more capable of ensuring technological precaution.

5.2.3 Regulatory Structure: Vertical v. Horizontal Regulations

Closely associated with the products v. processes debate, is the decision to regulate biotechnology according to existing, vertical regulations or via new, horizontal legislation. Regulating products of biotechnology is congruent with the existing, vertical regulatory jurisdictions in most countries. The key result is that existing vertical jurisdictions may be used to regulate GM crops, building on the accumulated expertise, capacity and trust in vertical agencies. This is the approach supported by economic interests because it is viewed as the best way to ensure technological progress.

On the other hand, regulating the process usually requires the development of new horizontal regulations which can address issues that existing, vertical structures may not. Given that the fundamental features of biotechnology remain virtually the same regardless of the application, regulating the technology potentially provides a more integrated approach than using divergent regulations in different vertical agencies. As the mandates of vertical regulatory agencies in most cases were developed prior to the biotechnological revolution it is argued that they were not designed to address the risks associated with this new technology (Rogers, 1990). A new, horizontal regulatory approach focused on the technology could possibly provide a more appropriate level of oversight, regardless of the product application. New horizontal regulations, however, face the inevitable political challenges of appeasing all actors, which is time-intensive and can lead to over-regulation and anti-competitive restrictions on the market (Cantley, 1998).

5.2.4 Regulatory Decision-Making in Risk Management

There are two aspects of regulatory decision-making to consider (1) the type of decision-making procedure employed and (2) the participation in the decision-making procedure.

With respect to the type of decision-making procedure, it can be either judicial or consensual. Judicial regulatory decision-making is done, for instance, through voting procedures among all the participants or among appointed 'judges'. After hearing the scientific evidence, a judgement is taken. Consensual decision-making, on the other hand, requires the unanimous support of all participants before regulations may be enacted.

Similarly, with respect to the participation in the regulatory decision-making procedure, it can be either the narrow participation of 'experts' or the broad participation of a wide range of actors. For instance, in a traditional, vertical independent regulatory jurisdiction, such as agriculture, regulatory development and decision-making generally has a narrow set of involved actors such as farmers and agro-chemical companies. Issues associated with the regulation of GM crops have tended to dramatically increase the number of interested actors because of the broad range of consumer concerns involved. The greater the number of actors, the greater will be the number of competing interests and, by implication, the regulatory decision-making procedure will be more complex.

In Table 5.1 is a cross-comparison of regulatory decision-making. In general, judicial decision-making creates winners and losers however it circumvents the need to build unanimity. Judicial and narrow decision-making is the most timely and specific type of decision-making, although it lacks credibility because it is exclusive and elitist. In fact, the discussion on the Codex (3.2.1.C) revealed that Codex decision-making has shifted from a consensual to a judicial basis because of the linking with trade agreements causing criticism about its credibility in establishing harmonised international regulations. In contrast, consensual and wide decision-making is the most credible because it is inclusive, however it is time-intensive and lacks specificity with so many interests and concerns involved.

	Narrow Participation	**Wide Participation**
Judicial/Voting	Most Timely Winners and losers Elitist/Exclusive (WTO DSM, Can, US, IPPC DSM)	Winners and losers (EC Parliament Vote)
Consensual	 (OECD, Codex, IPPC IPSMs)	Most Time-intensive Credible/Inclusive (BSP, Other UN Initiatives)

Table 5.1 Regulatory Risk Management Decision-Making

5.2.5 Regulatory Instruments: Mandatory Labelling Policies

Labelling is a risk communication tool, along with public service announcements, advertisements and public seminars, that transfers knowledge from the supply-side to the demand-side of the market (Phillips and Isaac, 1998; Caswell, 1999). Labelling is often a voluntary private instrument that firms are both able and willing to pursue in order to differentiate their products in the market place. Voluntary labels require a consumer willingness to search out and to pay for the differentiated products.

Labelling may also be a mandatory public instrument. In fact, mandatory labelling regulations for products made from GM crops are currently an important principle for the development of overall GM crop regulations because many states have developed or are developing mandatory schemes.

There are two motivations for mandatory labelling schemes: labelling for safety reasons or labelling for the consumer's right to know. The former is the traditional approach, where the label is used to connote some kind of safety or health risk from the product, such as warning labels on cigarette packages or labelling the presence of allergens in a food product. In the absence of any hypothetical safety risks, GM labelling schemes are often justified as meeting the consumer's right to know that GM crops have been used in the processing or production of the food product. There are both advantages and disadvantages to mandatory labelling schemes based on the consumers' right to know. It is advantageous in the sense that it meets a consumer demand to know whether the food product contains or has been derived from any GM material. It provides for informed consumerism because it is information that can build trust and ensure choice. However, labels not based on health and safety information are normative social statements appeasing only those interests who have raised speculative, unsubstantiated claims. This provides undeserved credibility to the critics and creates the misimpression that GM crops and foods are unsafe or inferior to conventional products.

The UK has adopted a mandatory labelling scheme based on the consumers' right to know, not based on safety considerations. This is a second best policy in the sense that it is a reaction to public fears, not to safety. The cost burden falls on the retail food outlets (supermarkets, caterers, restaurants, etc.) who are on the front-line between producers and consumers. Therefore, this second best labelling policy for the consumer's right to know, has lead to an inequitable distribution of costs. Further,

given the credence nature of GM crops, there is a practical issue associated with labelling for the consumer's right to know; does a label indicating the presence or possible presence of GM material really allow for informed choice? While the label would allow consumers to know, it does not add to true informed choice because as shown in Chapter 2 overall consumers still remain uninformed about GM crops.

Recent research supports the importance of labelling to meet the consumer's right to know and it concluded that choice is paramount for consumers' risk perception. It also concludes, however, that in the case of rbST in milk, labelling brought premiums for the voluntary label on non-rbST products (Zepeda et al 1999). The implication of this analysis is that a voluntary label for non-GM foods is both economically more efficient and consumer beneficial than a mandatory labelling scheme not rooted in health or safety concerns. A voluntary labelling program would more equitably distribute the costs of labelling according to consumers' willingness to pay for GM-free alternatives. Based on this logic, in the US, the American Corn Growers Association (ACGA) is developing a voluntary, GM-Free crop certification scheme, supported also by the National Grain and Feed Association (NGFA)(World Food Monthly No. 19, 1999).

5.2.6 Summary of Regulatory Debates

Together, the debates associated with the general and specific GM crop regulatory principles reveal two distinct regulatory paradigms – a scientific rationality paradigm and a social rationality paradigm. Essentially, these two paradigms establish the regulatory parameters of a jurisdiction and the precise regulatory approach must strike a politically acceptable balance within these parameters (Table 5.2).

There are two crucial features of the GM crop regulatory development process. First, and perhaps the most important feature is that the fundamental regulatory principles have not been established. For instance, the definition of 'risk' for regulating new technologies or the applicability of the substantial equivalence principle in regulations remain highly contentious debates. As a result, GM crop regulations are unstable as various economic and social interests lobby for either the scientific or the social rationality approach. Moreover, the regulatory instability associated with GM crops at national as well as international levels is a unique feature distinct from other social regulatory barrier issues. For instance, while the transatlantic trade of beef products has been controversial on health and safety grounds, at least the

fundamental regulatory principles for regulating beef safety are very much universal (Spriggs and Isaac, In Press). Until the fundamental principles are established, regulatory instability will remain and GM crop regulations will shift within the regulatory parameters according to the influence of the competing interests.

	Scientific Rationality	Social Rationality
General Regulatory Issues		
Belief	Technological progress: Enhances growth and development leading to higher social regulations – a regulatory race to the top.	Technological precaution: Technology cannot be separated from socio-economic factors – must be socially responsive.
Type of Risk	Recognised Hypothetical	Recognised Hypothetical *and* Speculative
Substantial Equivalence	Yes	No
Science or Other in Risk Assessment	First regulatory hurdle based on identified safety or hazard risk	All four regulatory hurdles
Burden of Proof	Traditional: Minimise Type I (Rejected when safe)	Minimise Type II (Accepted when unsafe)
Risk tolerance	Minimum	Zero tolerance
Science or Other in Risk Management	Safety or Hazard-based Risk Management is for risk reduction and prevention only	Broader socio-economic concerns Risk Management is for social responsiveness
Specific Regulatory Issues		
Precautionary Principle	Scientific Interpretation	Social Interpretation
Focus	Product-based, Novel Applications	Process- or Technology-based
Structure	Vertical, Existing structures	Horizontal, new structures
Participation	- Narrow, technical experts - Judicial decision-making	- wide: 'social dimensions' - Judicial decision-making
Labelling	Safety or Hazard only Voluntary, market-based for the consumers' right to know	Mandatory, process-based for the consumers' right to know.

Table 5.2 Comparison of Scientific and Social Rationality Regulatory Approaches

Another crucial feature of the GM crop regulatory development process is the path dependency of the regulatory paradigms. Initially, the particular regulatory trajectory is determined by the independence and discretion of the regulators and the role of science in the regulatory development process. If scientific rationality is the tradition, then subsequent regulatory principles tend to hold an important role for science in determining the appropriate level of regulatory oversight. Conversely, if social rationality is the main paradigm, then subsequent regulatory principles tend focus more on social responsiveness despite the scientific underpinnings for the regulatory stance. In addition, the path dependency is also influenced by the competitive position of the jurisdiction state in the new technology. A commercialisation lead affords a jurisdiction more time to become acquainted with the

credence factors of a new technology and may even allow the unknown risks to become known. On the other hand, a commercialisation lag ill-prepares the consumers within a jurisdiction for the sudden appearance of advanced technologies developed elsewhere.

Once established, the regulatory trajectory is influenced by the dominant interests in the regulatory development process. For instance, dominant social interests in an otherwise traditionally scientifically rational jurisdiction may be compel a social rationality regulatory response. When both economic and social interests have influence, such as in the case of GM crops, regulatory instability is certain to emerge.

The path dependency of GM crop regulations makes it difficult to integrate the two paradigms. For instance, a regulatory trajectory focused on technology-based oversight is difficult to combine with a trajectory focused on application or product-based legislation according to novelty. Similarly, substantial equivalence can be either accepted or rejected within a jurisdiction; there is really no middle ground with this regulatory principle.

The two distinct paradigms along with the regulatory debates identified in Table 5.2 can be used to characterise the GM crop regulatory development process within a regulatory jurisdiction. In order to do so, the commercial position of the jurisdiction, the traditional regulatory role of the state, the influence of the various economic and social interests must be identified. This will be done for the North American and the European Union's regulatory approaches in Chapters 6 and 7, respectively. However, prior to this, it is now vital to link the regulatory approach with the integration strategy. This is the objective of the next section.

5.3 Regulatory Integration

While two jurisdictions may claim to have Risk Analysis-based GM crop regulations employing the precautionary principle, the previous sections have revealed that their approaches may be drastically different. The result is the creation of social regulatory barriers and regulatory regionalism as GM crops approved for market access in one jurisdiction face regulatory delay and perhaps rejection under the regulatory approach within another jurisdiction.

Social regulatory barriers represent a trade challenge quite unlike traditional border measures such as tariffs and quotas, which tend to be quantitative, easily identifiable and driven by commercial protectionism. Instead, social regulatory

barriers are non-quantitative and involve social preferences and concerns. Regulations for food safety and environmental protection tend to be inwardly focused, reacting only to domestic interests with little tradition for considering their potential market access impacts. Although regulatory barriers to trade are at present a limited source of market access barrier[9], their use in the trade of GM crops is already a significant transatlantic trade tension.

In this section, the prospects for the integration of GM crop regulations, given the possible divergence in approaches between jurisdictions, are examined. Essentially, regulatory integration is a function of the regulatory approach adopted. A scientific rationality approach to regulating GM crops tends to be congruent with an international economic integration strategy supported by the international trade regime. Alternatively, a social rationality approach tends to be congruent with an international social integration strategy incongruent with the traditional trade approach.

Therefore, social regulatory barriers incur a conflict between economic interests who support scientific rationality and shallow economic integration and social interests who support social rationality and deeper social integration. This regulatory integration conflict will be illustrated with reference to several trade disputes involving issues that may be reasonably extrapolated to disputes involving GM crop social regulatory barriers. Then, based on this analysis of the conflict over social regulatory barriers, the three choice parameters for regulatory integration identified in Chapter One will be assessed.

5.3.1 Analysis of Trade Agreements and GM Crop Measures

In order to illustrate the difference between economic and social integration strategies two trade dispute cases and one current trade tension are summarised. To control the development and commercialisation of GM crops some Members of the World Trade Organization have proposed regulatory measures such as an outright ban on GM crops and GM foods or mandatory labelling schemes for GM foods. Both food safety and environmental protection justifications have been cited to support these

[9] Roberts *et al.*, (1998) conclude from a comprehensive evaluation of market access barriers facing US agricultural exports that most barriers are imposed to protect the economic interests of domestic producers, not to protect the concerns of domestic consumers.

measures. Are these measures compatible with the rights and obligations of Members under the WTO?

These examples were chosen because they are relevant for potential food safety, environmental protection and labelling disputes over social regulatory barriers to GM crops. They will be examined in order to understand how food safety and environmental protection-type social regulatory barriers restricting market access for GM crops and GM foods may be dealt with according to the economic integration approach.

This assessment reveals the significant limitations of the economic integration approach when dealing with social regulatory barriers because of the failure to deal appropriately with social concerns. The implications of this on trade diplomacy efforts will be assessed following the case studies.

A. Food Safety Ban: EU and Canada – US Beef Hormones Dispute

The use of hormones in the production of beef has been a controversial issue in Europe for over twenty years. In March 1988, an EU Directive (88/146/EEC) banned the use of six hormones in beef production in both domestic and foreign (imported) beef products. The EC directive identified six separate growth hormones--three natural occurring ones (oestradiol-17ß, progesterone, and testosterone) and three synthetic ones (trenbolone acetate, zeranol and melengestrol acetate ("MGA")) and applied a zero-tolerance policy. As a result, North American beef containing such hormones was effectively prohibited from EC markets, regardless of the fact that hormone use had been approved as safe in North America.

In 1988, the ban was not in violation of the GATT 1948 because it was being applied according to the principles of non-discrimination. In 1995, when the WTO came into force, those Parties of Export who felt that the ban was scientifically unjustified protectionism now had the legitimate opportunity to challenge the ban under the safety-related provisions of the SPS Agreement.

Canada and the US complained, on behalf of beef producers, to the WTO that the EU regulations against beef imports into Europe treated with growth hormones violated the EU's obligations under the SPS Agreement[10]. They argued that the ban was not consistent with Codex standards and that there was insufficient scientific

[10] European Communities - Measures Concerning Meat and Meat Products (Hormones); Panel, 18 August 1997; Appeal 16 January 1998; Arbitration; 29 May 1998.

justification for the EU to impose a standard higher than the Codex standard. The Codex ruled, in 1995, on the maximum residue limits for the safe use of these hormones in beef production (CAC, 1995; McDondald, 1998). Similarly, in 1995, an EU conference reported that the hormones were safe and within normal physiological ranges (Europe Drug and Device Letter, 5 February 1996). Yet, despite the advice from its own scientists, the European Commission maintained the ban.

The WTO dispute panel decision ruled against the EU ban, and the EU promptly appealed the decision. In its decision, the Appellate Body of the WTO was careful to argue that its decision was a 'procedural ruling' on the basis of the wording of the SPS Agreement and not a decision about the permissible use of health and safety regulations by Members. In fact, it has been argued that the Appellate Body does make efforts to uphold the sovereignty rights of Members when making decisions about their obligations under the trade agreements (Jackson, 1997).

The Appellate Body ultimately held that the EC directive did violate the SPS Agreement, because the measures were not based on an appropriate risk assessment and were not scientifically justifiable. No risk assessment had been done for the MGA hormone and scientific evidence from both North America and Europe along with the Codex standard suggested that the other five hormones were safe if properly administered. The evidence presented concerning the carcinogenic potential of increased hormone ingestion was found to be unrelated to the six hormones in question. The panel also found no evidence that any of the six hormones were being improperly administered on a widespread basis.

Further, the Appellate Body also considered the justification for the ban under SPS Article 5:7, the use of the precautionary principle. This was found to be an insufficient justification because (1) a provisional ban must be temporary while the ban was a permanent EU Directive, (2) the ban is justified if there is insufficient scientific evidence, yet there were numerous scientific studies from both Europe and North America. On this matter, the Appellate Body concluded that "the precautionary principle has not been written into the SPS Agreement as a grounds for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement" (Appellate Body Ruling Article 124).

The ruling may be interpreted as requiring Members to employ the scientific interpretation of the precautionary principle. That is, Members must prove more than just public fear to support a claim of precaution. Instead, hypothetical risk assessments

or highly conflictive scientific conclusions are an appropriate justification. In the hormones case, even the EU scientists found no evidence to justify the ban. The Appellate Body of the WTO therefore ruled against the EU ban and the EU's use of the social interpretation of the precautionary principle, recommending that the EU bring its measures into conformity with its SPS obligations.

This order has yet to be implemented. The EU informed the WTO that it must complete a new risk assessment and then implement new SPS measures to continue to ban hormone-treated beef. An arbitrator had ordered that the EU must comply with the panel ruling within 15 months; which was by 18 May 1999.

The WTO Appellate Body ruling raises the question as to what is a sufficient scientific risk assessment under the WTO? With respect to the regulatory debates assessed above the answer is that a legitimate risk assessment must be a comprehensive hypothetical risk assessment focused on the identifiable hazards to support the trade-restricting measure. Risk assessments based on vague, non-specific speculative risks or the social interpretation of the precautionary principle would not be deemed legitimate assessments according to these principles.

An important point is that the economic integration approach of the WTO is directly in conflict with the social integration approach supported by the European Court of Justice (ECJ). For instance, ECJ decided in favour of the ban because it was willing to consider the validity of non-science and non-safety objectives. The ECJ ruling claimed "traders were not entitled to expect that a prohibition on administering the substances under question to animals could be based on scientific data alone" (Scott, 1998). This difference should be expected because while the WTO is pursuing the traditional trade model of shallow, economic integration the role of ECJ is to facilitate the deeper social integration of EU Member States. In this sense, the ECJ *should* be considering broader socio-economic issues, while such issues are not in the remit of the WTO.

By extension, any EU ban on GM foods must fulfil the same scientific justification and risk assessment requirements in order to be trade compliant. Scientists in North America and in Europe have consistently argued that there are no justifiable grounds for banning GM foods on the basis of food safety concerns, other than the conventional concerns about allergens that are associated with non-GM foods as well. In fact, in most cases the unilateral bans by EU Member States on particular GM crops have resulted from politicians over-ruling the advice of their own scientific

advisory committees, because of consumer concern (see Chapter 7). Therefore, at the present time, an EU ban on GM foods appears to violate the WTO's SPS Agreement because there is not a sufficient scientific justification to declare that GM foods are unsafe.

Such a WTO decision on social regulatory barriers would surely be condemned by social interests for three reasons. First, it adopts a rigid scientific rationality approach to Risk Analysis requiring a focus on hypothetical, not speculative risks. Second, it limits the social responsiveness of risk management because it requires the evidence of actual risk to impose a ban, not simply perceived risk. Third, and perhaps most crucially, it supports the scientific interpretation of the precautionary principle over the social interpretation favoured by social interests.

B. Environmental Protection Ban: Tuna-Dolphin and Shrimp-Turtle

The Tuna-Dolphin trade dispute was based on a Mexican challenge to a US import ban on tuna products where so-called dolphin-friendly catch techniques had not been used. The US cited evidence about the recognised risk of certain tuna catch techniques on dolphin mortality rates and concluded that certain techniques were unacceptably risky. Consequently, tuna products in which the risky techniques were used faced an import ban. The dispute was pre-WTO and it went before the dispute settlement mechanism of the GATT.

Essentially, the US import ban was an environmental protection measure taken against the non-product-related PPMs of imported products. The method of catch had no impact at all upon the safety or quality of the tuna product, instead it had an environmental impact upon dolphins. The tuna imports were targeted with a second-best measure; an import ban designed to send a signal that US consumers prefer dolphin-friendly catch techniques.

The GATT dispute panel found in favour of Mexico. The ruling, congruent with the scientific rationality paradigm, concluded that the US had violated its GATT obligations by imposing a discriminatory import ban according to non-product-related PPMs. The ruling was sympathetic with US environmental preferences however, and suggested that a voluntary 'tuna-friendly' labelling scheme was the first-best measure to signal to consumers which non-product-related PPM had been used in the tuna catch. Such a scheme met two important criteria. First, it was a first-best and market-based strategy and second, it avoided the use of unjustifiable trade barriers based on

non-product-related PPMs and the extra-territorial extension of environmental preferences.

Similarly, the Shrimp-Turtle trade dispute was based on a challenge, brought to the WTO by India, Malaysia, Pakistan and Thailand, to a US import ban on shrimp that were caught in nets that also caught and killed sea turtles. Similar to the Tuna-Dolphin case, the Shrimp-Turtle import ban was based on the non-product-related PPMs of a traded product. The DSB panel ruled against the US import ban, which the US appealed. The WTO Appellate Body ruled that the US import ban violated the TBT Agreement by imposing a discriminatory trade ban according to non-product-related PPMs. Again the alternative suggestion was a voluntary labelling scheme. Additionally, the Appellate Body suggested that the involved countries could negotiate a multilateral environmental agreement (MEA) based primarily on the environmental concerns, outside the WTO framework.

Both cases reveal that environmental trade measures based on preferences for non-product related PPMs are not consistent with the rights and obligations of the international trade agreements. According to the WTO, a Member cannot unilaterally impose second-best extra-territorial environmental preferences for non-product-related PPMs upon other Members because this violates the non-discrimination principle and the product focus of trade agreements. Instead, two alternatives are more effective. First, is a voluntary labelling scheme connoting that a product has used an environmentally acceptable non-product-related PPM. Second, is a MEA pertaining explicitly to the environmental concern at issue as a first-best measure to address the environmental problem.

By extension, these cases suggest that an outright import ban on GM crops based on non-safety-related environmental protection justifications is not a trade compliant strategy. First of all, there remains significant uncertainty about whether transgenic modifications to crops are even non-product-related PPMs (see Chapter 3). Second, supposing that transgenic modifications were considered to be PPMs, the approved GM varieties have been approved on the basis of substantial equivalence, hence, the PPMs would be non-product-related. According to both the Tuna-Dolphin and the Shrimp-Turtle trade dispute rulings, an environmental protection ban based on non-product-related PPMs is not trade compliant and an environmental protection ban on GM crops based on a preference for non-GM PPMs is likely to be found non-trade compliant as well. The alternative then is a voluntary labelling scheme to connote the

use of a non-product-related PPM, which is examined below, or a MEA such as the Biosafety Protocol (see Chapter 4.2).

Caution must be taken, however, in extending the Tuna-Dolphin and Shrimp-Turtle cases to GM crops. The reason for this is because of the unresolved controversy surrounding the social interpretation of the precautionary principle in environmental protection objectives. In the cases of Tuna-Dolphin and Shrimp-Turtle the recognised risk of either dolphin or turtle unfriendly techniques to their mortality was known. With GM crops, many of the environmental concerns used to support an outright ban are based on speculative risks, not recognised or hypothetical risks. Unlike food safety issues, environmental protection issues traditionally and legitimately use the social interpretation of the precautionary principle in risk management. Therefore, while food safety justifications must employ hypothetical risk assessments and the scientific interpretation of the precautionary principle, non-safety-related environmental protection justifications in reaction to speculative risks – some of which may be of dread consequence – may employ the social interpretation of the precautionary principle, permitting a much broader justification for a trade ban in order to protect environmental biodiversity.

In addition, an environmental protection ban against GM crops justified as protecting the safety of plants, natural fauna, etc. would fall under the jurisdiction of the SPS Agreement. In such a case, the regulations would have to meet the scientific justification requirements established by the IPPC. Similar to a food safety ban, an environmental plant safety-type ban on GM crops must be based on hypothetical risks, focused on safety only and with no scope fro the use of the social interpretation of the precautionary principle. To date, there is insufficient scientific evidence that GM crops pose an environmental plant safety risk necessary to justify such a ban.

Therefore, an environmental protection ban on GM crops, either safety or non-safety-related, would likely violate trade agreements. Yet such a decision would be widely condemned by social interests. In this case, the lack of legitimacy given to domestic environmental preferences (non-product-related PPMs) under the traditional trade framework would be an important source of dissatisfaction because it fails to account for normative preferences in the regulatory measures. The analysis of the trade approach to an environmental ban also highlights the different interpretations of the precautionary principle. Again, the economic integration approach essentially rejects the social interpretation.

C. Labelling GM Foods

The labelling of products of modern biotechnology is an important regulatory integration issue currently facing Codex. Labelling polices are being developed by Member governments without the international guidance of Codex, which has yet to establish a Codex standard on this issue (see Chapter 3.2.1.C). In the EU, there have been pressures for a mandatory and comprehensive labelling policy for all food products produced from GM ingredients as a means of controlling the use of GM crops in the food supply (see Chapter 7). The purpose of this section is to examine the relationship between such a labelling policy and the Codex, the SPS Agreement and the TBT Agreement; is such a labelling policy trade compliant?

There are two important aspects of labelling to consider. Labelling for food safety reasons, such as for the presence of allergens, is an SPS issues. Labelling for non-food safety reasons such as the consumers' right to know is a TBT issue.

With respect to mandatory labelling for food safety reasons, such a policy would require a scientific justification for declaring foods produced from GM ingredients to be unsafe, similar to the food safety ban discussed in A, above. If there exists evidence that foods produced from GM crops are unsafe, however, then the first-best measure would be a ban, not a labelling strategy. The discussion in regards to a ban on foods produced from GM ingredients is relevant here. Again, as there seems to be insufficient scientific justification for a safety-related ban, a mandatory labelling measure based on the safety of GM foods would not be in compliance with the SPS Agreement.

With respect to mandatory labelling for the consumers' right to know, a label would indicate that the product is made of GM material or was exposed to GM material during the production process. If there is no evidence that such food products are unsafe, but consumers remained concerned, then the first-best policy is to label the products based on the consumers' right to know. The controversy arises because the consumer's right to know is not a universal justification for labelling. Consider two cases, the approved GM ingredient, rennet[11] widely in cheese production in Europe and the GM bakers' yeast approved for use in the UK in 1990. In both cases, the GM

[11] Rennet is a natural enzyme found in the stomach of veal calves and used in cheese making. A GM micro-organism with a duplicated calf gene codes for the enzyme which can then be industrially produced via fermentation rather than harvested from the gut of slaughtered calves (Harlander, 1993).

version was considered to be substantially equivalent to the conventional version, and there were no labelling requirements justified by the consumers' right to know about the use of either GM rennet or yeast.

The precedence for labelling based on the consumers' right to know about a food's process or production method has been established by the Codex guidelines on labelling irradiated meat products. But in the case of irradiated meat there is an agreed Codex standard. The Codex standard was agreed in 1983 and amended in 1989. The issue of labelling GM foods at Codex has not produced a Codex guideline that supports the consumer's right to know. In fact, the only Codex recommendation on the issue, from the Codex Secretariat, supports labelling only for novel GM products, not for the consumer's right to know about process and production methods for non-safety reasons.

The Codex Committee on Food Labelling (CCFL), currently chaired by Canada, considers international food labelling issues; drafts labelling provisions (and amendments) that are applicable to all foods; and, endorses labelling provisions in the standards, codes of practice, guidelines and recommendations prepared by other Codex Committees. The CCFL has discussed the labelling of biotechnology products at five separate meetings without reaching a conclusive Codex position. At the first meeting (October 1994) the key issue was whether to develop a mandatory and comprehensive label scheme to apply to all foods derived from biotechnology or to apply only to novel products. On one hand, Australia, Canada and the US argued that the science and safety-based Codex was not the proper venue for consideration of the consumers' right to know product information about social preferences over process and production methods. On the other hand, the EU position supported by the consumer and environmental organisations, was that social preferences could not be separated from food standards. In 1995, at the request of the CCFL, the US produced a position paper on biotechnology labelling which argued for a case-by-case, product-based approach to labelling, not a broad mandatory policy on labelling the use of modern biotechnology in food production (Horton, 1997). At the 43rd Session of the Codex Executive Committee, the issue of mandatory labelling for other than safety reasons was also considered, but with no resolution (CEC, 1996).

At the second meeting (May 1996), the two general positions were reiterated. The CCFL requested that the Codex Secretariat prepare a discussion draft on the biotechnology labelling issue for the next meeting.

At the third meeting (October 1997) the Codex Secretariat's discussion draft was presented. The two crucial recommendations from the Codex Secretariat were (1) labelling should only cover non-equivalent or novel products, and (2) labelling should focus on health risks including allergens. These recommendations were very consistent with the scientific rationality position on labelling only novel products, and they did not support the consumers' right to know as a justification for a mandatory labelling policy. But other delegations could not agree to these recommendations. Little progress was made at the fourth meeting in May 1998. Some leading agricultural exporters, such as Australia, Brazil, Canada, New Zealand, Peru and the US supported the adoption of both proposals but many European delegations along with India continued to block agreement.

At the latest meetings of the CCFL, in April 1999, there was still no success in establishing a Codex standard on a mandatory labelling policy for foods produced through modern biotechnology techniques. The US delegation, along with major agricultural exporters reasserted support for the Codex Secretariat's recommendations. The German delegation, on behalf of the EU, supported a mandatory comprehensive labelling policy based on the use of biotechnology. Many delegations informed the Codex Committee that they were unilaterally developing mandatory labelling policies for the consumers' right to know, with or without the endorsement of Codex. They argued that essential or substantial equivalence was a useless term when the justification was the consumers' right to know. Consumers' International (CI), argued that the consumers' right to know must be the basis for the Codex labelling policy (Consumers' International, 1999a), as it was with irradiated meat. CI also supported the alteration of terminology to focus on GM, not on the use of modern biotechnology in general (Consumers' International, 1999b). The Canadian hosts of the CCFL proposed that the ambiguity around the use of the term substantial or essential equivalence should be clarified by a working group (CAC, 1999).

The regulatory integration issues associated with labelling GM foods is also on the agenda of the TBT Committee. Technical labelling requirements are justified under the TBT Agreement according to the protection of consumer health and safety and according to the consumers' right to know in order to prevent deceptive practices. The US has submitted a request to the EU and the WTO's TBT Committee that the regulation be amended to reflect the trade concerns of the US and other agricultural exporters such as Australia, Canada and New Zealand. The submission claims that the

EU regulation (1) does not achieve a legitimate objective and (2) that the implementation of the regulation is problematic and creates an unjustifiable barrier to trade. With respect to the first claim, the US argues that GM crops do not differ as a class from conventional varieties. As other GM techniques, besides transgenic modification, such as mutageneisis and somoclonal variation, do not have to be labelled as such, there is no justification for differentiating transgenic crop varieties. With respect to the second claim, the US argues that the regulation is not non-discriminatory as required under the TBT Agreement as it would discriminate between those exporters where GM crops are produced and exporters where GM crops are not produced. Further, with respect to the 1% tolerance threshold for adventitious contamination agreed in the EU, the US is concerned that there is a lack of both standardised and accurate testing methodologies so that different tests will produce different test results. In the event that testing methods between jurisdictions differ, this raises concerns about the liability of a positive test and, perhaps, a rejection of an export shipment.

Therefore, although not consensual, the current Codex Secretariat recommendation for the mandatory labelling of biotechnology-based products supports labelling for novel products only, not for the consumers' right to know about non-safety process and production methods. Recall, all Codex standards, codes, guidelines and recommendations are considered 'standards' according to both the SPS and TBT Agreements. As a result, the establishment of a mandatory comprehensive and extensive labelling scheme is sure to initiate a trade challenge, and in all likelihood would be found non-compliant with the WTO for two reasons. First, there would be insufficient scientific justification for a mandatory labelling policy based on food safety concerns under the SPS Agreement. Second, the labelling recommendation of the Codex Secretariat does not support the use of a mandatory comprehensive labelling policy for the consumers' right to know non-safety issues. Additionally, although a voluntary labelling scheme for products made from GM crops would be compliant with trade rules, a voluntary scheme is unlikely to be acceptable to social interests because it would lack the sanctions to ensure that the consumers' right to know is met.

There does exist a curious situation in EU-US discussions over labelling. While the EU demands the labelling of foods produced from GM ingredients based on the consumers' right to know, it has rejected US offers to label hormone-treated beef

as 'US beef' in order to meet the consumers' right to know. The US beef label would connote to European consumers that it is hormone-treated beef without appearing as an hazard warning similar to warnings about the presence of nuts in food products.

D. Discussion: Implications for Trade Diplomacy

It appears that both an outright ban on the use of GM products, on either food safety or environmental protection grounds, and a mandatory and comprehensive labelling scheme would contravene international trade law. Yet, a WTO decision against either a ban or a comprehensive labelling scheme would essentially be a ruling against the social rationality approach to regulations including the social interpretation of the precautionary principle and the right to consider other legitimate factors such as consumer concerns which may not be grounded in scientific evidence.

Given the distinct conflict between economic and social interests, the objective is to assess the implications upon traditional trade diplomacy. Can the WTO approach (embodying its agreements and affiliated international institutions) facilitate the integration of food safety and environmental protection regulations for GM crops in order to prevent social regulatory barriers to trade? While there are strengths to the WTO approach there remain crucial weaknesses, which seem to indicate that the economic integration approach of the WTO cannot, and indeed should not, facilitate social regulatory integration. In other words, trade diplomacy must be amended if it is to remain a viable force in the international integration of GM crop regulations.

On one hand, there appears to be several strengths of the WTO in facilitating regulatory integration. Indeed, there is support for this role of the WTO (Buckingham *et al.*, 1999; Perdikis *et al.*, 1999). In general, the WTO is institutionally more capable of facilitating the centralisation of domestic regulatory policies in order to encourage trade liberalisation, than was the international trade regime under the GATT 1948. There are three aspects to note. First, membership in the WTO is an important national priority where Members take the objective of trade liberalisation and the ensuing rights and obligations of membership very seriously. Indeed, gaining membership is an important priority for non-Member states (i.e. Russia and China). Second, the Dispute Settlement Mechanism, with its binding decisions, is better equipped to more equitably deal with the market access disputes that contravene the rights and obligations of WTO Members (Jackson, 1996). In fact, since many of the disputes have involved either the EU or the US (or both), the panels are often composed of

smaller country representatives who have exercised important influence over DSB precedence so far. Also, as the dispute settlement decisions are binding, despite their power, the US and the EU are compelled to fulfil the obligations of a panel decision rather than employing the 'might is right' principle. Consider both the Tuna-Dolphin and the Shrimp-Turtle disputes. The US lost both disputes to developing countries. In this sense, under the DSB, the obligations of the WTO are a gift from the strong Members to the weak Members. Third, the Agreements on Agriculture, TBT and SPS measures have clarified the permissible role of national governments in establishing regulations with potential trade impacts.

With respect to food safety specifically, the SPS Agreement is a rules-based agreement focused on hypothetical risk assessment and employing the scientific interpretation of the precautionary principle. According to this approach there is certainty and stability built into the trade rules. There is considerable scope for Members to unilaterally impose social regulatory barriers provided they are scientifically justifiable.

With respect to environmental protection measures, the conviction of Members to honour their obligations possibly prevents Members from making environmental commitments that they don't keep, which has been a familiar complaint about multilateral environmental agreements. The WTO has considerable experience with multilateral agenda setting among often very divergent national interests. This experience could be channelled towards establishing an international environmental agenda. The primary benefit of this approach is that an internationally consistent, rules-based regime may be developed. This is a desirable outcome in the sense that it would lend real international discipline and certainty to very contested environmental protection issues and it would ensure that multilateral environmental externalities are dealt with. Additionally, any initiatives to come out of this framework would increase trade compatibility eliminating or reducing both market fragmentation and trade threats.

Yet, despite the apparent strengths, there are weaknesses with the WTO approach. Principally, it is an institution focused on trade liberalisation and based on the traditional trade model of economic integration and regulatory competition. Regulatory competition does not effectively deal with broader, populist issues as the struggles of the CTE indicate. Instead, the WTO's regulatory competition approach continues to encourage traditional, closed-door and non-transparent trade diplomacy.

In fact, despite a few high profile dispute resolution cases, most trade tensions are dealt with according to the traditional trade diplomacy model. The trade framework inappropriately deals with other legitimate objectives for regulatory development and regulatory barriers to trade will be evaluated according to trade principles – their sufficient scientific evidence and whether or not they minimise trade disruption – and not according to whether or not they achieve their legitimate social objectives. In short, regulations based on non-scientific justifications are unlikely to be found trade compliant, even though they may be both socially responsive and legitimate.

When disputes are taken to the WTO, DSB decisions are 'forced' on Members, creating winners and losers, increasing public dissatisfaction among losers and subsequently decreasing overall support for trade liberalisation efforts. In this context, it is difficult for Members to reject calls for unilateral protectionism since the trade agreements fail to accept socially responsive regulations.

With GM crops, trade protection is demanded by social interests while trade agreements have historically developed to deal with protectionist pressure from producers (Perdikis *et al.*, 1999). The question then arises; are some regulatory issues emotive enough that Members, or a group of Members, would tolerate non-compliance with the WTO rules? Such an outcome would have disastrous results for the institutional credibility and authority of the international trading regime. In fact, this has already happened with the EU – US beef hormone dispute where the EU is prepared to remain in permanent contravention of the WTO rules.

The scientific basis for justifiable regulations and the scientific interpretation of the precautionary principle limit the political scope for domestic regulators to respond to public concern. During the risk management process economic trade analysis often concludes that 'science' will be the final arbiter of trade disputes (see Jackson, 1999; Buckingham *et al.*, 1999). Yet, there is no agreement on the legitimate and credible role of science. A common argument against the scientific basis of WTO agreements and the DSB decisions is that they are crucially flawed. They rely on international organisations, such as the Codex, to develop international standards. The Codex, however, can no longer be interpreted as establishing consensual international standards because it has adopted judicial (voting) decision-making that creates winners and losers and does not reflect international consensus. The focus on science has created a 'your scientist' v. 'my scientist' ethos where trade lawyers will define appropriate science, food safety and environmental protection regulations.

EU regulators, along with some of its Member States, have continually ignored the advice of its own scientists over beef-hormones, antibiotics and GM crop approvals in an effort to be seen as socially responsive. The WTO's scientific rationality approach does not accommodate the social rationales such as the social interpretation of the precautionary principle in risk management. A WTO decision against either a ban or a comprehensive labelling scheme would essentially be a ruling against (1) the social interpretation of the precautionary principle, (2) the consumers' right to know about a product's PPMs and (3) the right to consider other legitimate factors such as consumer concerns that may not be grounded in scientific evidence. As these are considered to be 'unalienable rights' within the social rationality approach such a decision would lead to condemnation of the WTO from social interests.

With respect to environmental protection measures there are several specific weaknesses of the WTO. First, trade objectives may not be consistent with environmental objectives and in the event that the objectives are not congruent, trade objectives will dominate. Second, the WTO lacks credible environmental expertise or the legitimacy to adjudicate environmental disputes (Economist, 9 Oct. 1999) and the CTE has struggled to develop a rigorous environmental agenda. Third, as a multilateral institution focused on 'top-down' approaches to enhancing trade, the WTO may be insensitive to legitimate national differences in environmental concerns, which are the basis for national environmental protection measures. Fourth, developing a 'top-down' environmental agenda acceptable to all Members at varying levels of development risks the establishment of an agenda that reflects the lowest common denominator approach rather than the establishment of an agenda that reflects the highest environmental standards. Fifth, the science-based approach to phyto-sanitary measures under the IPPC is in conflict with traditional environmental approach employing the social interpretation of the precautionary principle. Sixth, the WTO provides inadequate participation in decision-making for social interests such as consumer and environmental organisations. The Members of the WTO are governments and it is expected that consumer and environmental organisations make their positions to the national delegations, not directly to the WTO. Social interests tend to argue, however, that WTO Members, who may all be approaching an issue from a narrow commercial or national self-interest point of view may collectively fail to appreciate the global externalities of environmental problems. Hence, they argue

that they should have full access to and participation in the WTO to ensure that the externalities are addressed.

Given these significant weaknesses, the WTO appears to have reached its level of competence and will be unable to support the international integration of food safety and environmental protection regulations and thus deal with social regulatory barriers as issues become increasingly socio-economic in nature and calls for protection emerge from non-traditional sources.

The question then arises, should the agreements be broadened in order to address these concerns? Or should new agreements under the WTO be established? Recent research argues that neither the SPS nor the TBT Agreements should be re-negotiated to incorporate these concerns (Perdikis *et al.*, 1999). Instead it is proposed that a separate Agreement on Trade Related Aspects of Consumer Concerns (TRACC) be negotiated within the WTO framework. Further, the international standards for this agreement would be established by a professional, social science based institution, the Commission on Consumer Issues and Trade.

The problem with the WTO framework is, however, much deeper than the limitations of the SPS and TBT Agreements. In fact, it is the traditional trade model and the regulatory competition paradigm which limits the WTO as a framework for facilitating social regulatory integration and it is unlikely that the WTO can shift enough within this paradigm to accommodate the broader concerns. To incorporate broader social dimensions would require deeper integration, which is not an objective of the traditional trade model. The proposals for new agreements in the WTO do nothing to address the fundamental principles of the organisation. For instance, the proposed TRACC and its affiliation with the Commission on Consumer Issues and Trade would be designed to facilitate ex post regulatory convergence through market competition and the dispute settlement mechanisms not ex ante regulatory co-ordination. The winners would still force regulatory convergence onto the losers. Further, although social interests have agreed on many aspects of GM crop regulations, it is a mistake to think of the organisations as a homogenous group (see Chapter 4). The groups petitioning the Commission on Consumer Issues and Trade on behalf of consumer concerns will range from those with cautious support for the WTO to those who want to see it drastically changed or even abolished. It is unlikely that an agreement within the WTO framework would be an acceptable or credible venue for

these groups. Without their participation it can be expected that their 'extremism' will continue outside the WTO.

Therefore, the WTO cannot effectively facilitate the international integration of GM crop regulations. The key issue is that when fundamental regulatory principles have not been established the WTO cannot develop top-down regulatory rules for risk assessment and risk management. Instead, dominant jurisdictions must establish their own approach subject to endogenous political economy factors and then seek to integrate that approach with other jurisdictions. In other words, while the WTO can remain effective at administering and monitoring regulatory rules, it cannot facilitate framework making. Every effort should be made by all Members to avoid bringing social regulatory barrier disputes to the WTO. This way, the WTO can continue its valuable trade liberalisation efforts, on behalf of Members without having to risk its credibility and legitimacy by making risk management judgements against the social regulatory approaches of Members.

5.3.2 GM Crop Regulatory Integration

In Chapter One (1.2.3) it was proposed that, with respect to social regulatory barriers, a regulatory jurisdiction faces three choice parameters for regulatory integration: level of integration, depth of integration, and strategy of integration (Fig. 5.1). These parameters may now be applied to the specific challenge of social regulatory barriers to GM crops, and they will be assessed in this order below.

		1. Integration Level	
		I. Global/Multilateral	II. Regional/Bilateral or Plurilateral
		3. Integration Strategy	
		Regulatory Competition	Regulatory Co-ordination
2. Integration Depth	Shallow 'Economic' Integration	**A**	**B**
	Deeper 'Social' Integration	**C**	**D**

Fig. 5.1: Integration Parameters Facing a Regulatory Jurisdiction

A. Level of Integration

This study proposes that the appropriate level of integration is the transatlantic level. There are several reasons for this. First, North American and European agricultural biotechnology firms have had the greatest capacity to develop and commercialise GM crops. As a result, both regions have had to develop regulatory

oversight in this rapidly expanding sector. Second, with high levels of income, both regions have implemented stringent income elastic social regulations for food safety and environmental protections. Third, transatlantic trade tensions play a pathfinder role for solving trade issues where frontier market access issues, such as social regulatory barriers, must be addressed at the transatlantic level before they can be effectively multilateralised (Woolcock, 1998). This is because while North American and European markets can normally compel other countries to unilaterally converge their regulations in order to gain market access, when the barriers are transatlantic these two regions cannot compel one another to converge, and thus, must embark on a dedicated integration strategy. In the absence of a consensual transatlantic regulatory approach it is virtually impossible to develop an international regulatory approach. Instead, international regulations for GM crops are a fragmented collection of standards, codes, guidelines and recommendations. Fourth, social regulatory barriers have already had significant trade impact with respect to the transatlantic dispute over hormone-treated beef.

Agricultural trade issues have been, and will continue to be significant impediments to multilateral trade negotiations (Scher, 1999; Wigan, 1998; Phillips, 1991; Kramer, 1989). It has been argued that agricultural competition has been at the heart of all EU-US agricultural trade disputes, not food safety or environmental protection (Coffey 1993; Lister 1996). Given the competition issues in both regions, agriculture will remain a highly protected sector despite recent attempts to introduce multilateral trade discipline through the Agreement on Agriculture of the WTO.

The growing regulatory regionalism produced by the North American and the European approaches to food safety and environmental protection may undermine efforts to develop a multilateral trading regime. In fact, the discussion on the Biosafety Protocol (Chapter 4.2) indicates the difficulties in international regulatory integration when there is no transatlantic consensus. These two regions have long been the pillars at the international level. Greater regulatory intransigence at the transatlantic level effectively prevents the establishment of a much needed co-ordinated international approach to regulating GM crops. Essentially, all other issues surrounding agricultural biotechnology are stalled until transatlantic co-ordination is achieved. Unfortunately, this includes the crucial North-South capacity gap and international concerns regarding the transboundary movement of living modified organisms and biopiracy. In this sense, establishing transatlantic regulatory co-

ordination is time-sensitive and vital to the economic development of less developed countries.

In order to understand the prospects for transatlantic regulatory integration, it is useful to discuss the transatlantic relationship with respect to social regulations as well as biotechnology. Traditionally, transatlantic economic relations have been regarded as a part of the larger strategic agenda of managing the global economic order to promote security and stability (Frost, 1998). From this perspective, the 'low politics' of economic relations are inherently linked to the 'high politics' of global security and stability, as increased trade produces increased prosperity which, in turn, produces economic and social stability. Indeed, Article 2 of the 1949 NATO Charter commits members "to seek to eliminate conflict in their economic policies" and encourages "economic collaboration between any or all of them" as part of the broader strategic objective (Frost, 1998). However, is this link between low and high politics still a factor? Recent transatlantic trade tensions involving bananas and hormone-treated beef have occurred during UN action in the Gulf and NATO action in Yugoslavia, suggesting that the link between the 'high politics' of global security and stability and the 'low politics' of transatlantic economic relations has become very weak.

In the past two decades, there have been several proposed initiatives between both Canada and the EU and the EU and the US designed to enhance transatlantic economic relations. In 1976, Canada and the EC completed the *Framework Agreement for Commercial and Economic Cooperation* designed to facilitate bilateral consultation on trade issues[12]. In fact, this agreement was the EC's first co-operation agreement with an industrialised nation. This was followed in 1990 with the *Transatlantic Declaration on EU-Canada Relations*. Similar to the 1976 Framework Agreement, the declaration was focused on facilitating bilateral consultation in order to promote both economic and political stability.

In Ottawa, Canada on 17 December 1996, Canada and the EU adopted the *Joint Political Declaration and Action Plan* which consists of four parts: economic and trade relations; foreign policy and security issues; transnational issues; and fostering further links. This Action Plan was an attempt to reinforce bilateral

[12] EU-Canada: A Solid Economic Relationship June 1999 (www.europa.eu.int/comm/dg01/eucanen4.htm) and EU-Canada: Historic Friends June 1999 (www.europa.eu.int/comm/dg01/eucanen1htm)

economic and political relations after several conflicts such as the beef hormones dispute and the Atlantic fisheries dispute between Canada and Spain. As a result, Canada –EU economic relations have been re-coupled with larger strategic issues.

Finally, the trade and economic relations component of the 1996 Action Plan was further developed into the 1998 EU-Canada Trade Initiative (ECTI). The ECTI established an agenda for bilateral economic and trade relations. Bilateral consultations have focused on broad frameworks for mutual recognition, equivalence and regulatory co-operation in areas of technical barriers to trade. For instance, the recent EU-Canada Veterinary Agreement 1999 is an example of a bilateral agreement based on the mutual recognition of sanitary measures applied in both Canada and the EU. The ECTI is held to be the vehicle for addressing bilateral trade friction associated with agricultural biotechnology products. Therefore, despite the economic and political focus of the 1996 Action Plan, it is the economic component which has received the most attention, again, decoupling low politics from high politics.

With respect to EU-US bilateral relations, the transatlantic tensions associated with agricultural liberalisation during the Uruguay Round of multilateral trade negotiations gave rise to three EU-US proposals. The first was the broad Transatlantic Declaration on EU-US Relations in 1990, which identified shared, long-term goals and linked the economic relations to political and security relations. The second initiative was the EEC-US Hague Summit in November 1991 followed closely by the third initiative, the EEC-US Declaration in West Berlin in December 1991. All three initiatives were aimed at breaking the agricultural impasse at the multilateral trade negotiations and together were successful efforts in economic diplomacy (Coffey, 1991).

In 1995, there were three EU-US proposals to enhance transatlantic relations. The Transatlantic Treaty proposal involved the establishment of a security, political and economic arrangement, effectively strengthening the link between economic relations and the political and security relations. This represented deep integration with formal and binding rules. There was also a proposal for a transatlantic free trade agreement (TAFTA). Supporters argued that there were three significant benefits from a TAFTA. First, the EU and the US are the most compatible markets with similar demands, tastes as well as social and political values (Gaster and Prestowitz, 1994). Second, a TAFTA would represent an inter-regional trade liberalisation strategy, removing the limitations of regulatory regionalism and enhancing multilateral trade

(Preeg, 1996). Third, efforts to enhance trade liberalisation between the two globally dominant regions would compel other protectionist states or regions to liberalise (Yeutter and Maruyapma, 1995). Critics argued that a TAFTA creates transatlantic regionalism built on similar income levels and social values that would both antagonise other countries and regions and harm the prospects for multilateral trade liberalisation (Bergsten, 1996). A TAFTA would have enhanced trade and economic cooperation, not deeper integration although it would have involved formal and binding rules. Finally in 1995 was the New Transatlantic Agenda (NTA) proposal, focused on promoting global peace, stability, democracy and economic development while both contributing to the expansion of world trade and enhancing transatlantic economic relations. One particular initiative of the NTA was to establish the New Transatlantic Marketplace (NTM). Within the NTM was a proposal to establish a US – EU biotechnology task force to encourage dialogue between the US FDA (see Chapter 6) and the EU DG III (Industry) (see Chapter 7). It is important to note that, as will be discussed in more detail below, the FDA and DG III agree on many fundamental principles about biotechnology regulations. The regulatory regionalism with respect to GM crops is the result of the dominance of DG XI (Environment) in EU regulations because DG XI has a much different regulatory philosophy than that adopted in North America. The NTA was a policy document with no binding discipline and as a result it lacked the power to compel both sides to address, in a meaningful way, the most contentious issues facing transatlantic economic relations (Wigan, 1998). The NTA represented a framework for shallow integration and formal and binding rules were absent. In this sense, the transatlantic proposals in 1995 indicate a marked shift from attempts to develop formal and binding integration across economic, social and political issues to attempts to simply outline a non-binding framework for shallow integration across primarily commercial or economic issues.

Coinciding with the NTA, were three separate initiatives; the Transatlantic Business Dialogue (TABD), the Transatlantic Consumers Dialogue (TACD) and the Transatlantic Environmental Dialogue (TAED). These initiatives sought to bring together relevant stakeholders in the three broad policy areas, including government, industry and non-governmental organisations, in order to address transatlantic issues. For instance, the TABD, established in Seville, Spain in November 1995, is an informal group of companies and industry associations who develop joint EU- US trade policy recommendations for dealing with regulatory barriers to trade from an

industry perspective. The TABD's 1997 Communiqué (Rome) noted that "our regulatory agencies can no longer continue to function solely on the basis of national considerations" and it urged the respective administrations to pursue regulatory harmonisation (Zampetti, In Press). However, it has been argued that TABD's attempts at resolving regulatory structural market access issues have only had limited success (Frost, 1998).

The most recent EU-US transatlantic initiative has been the Transatlantic Economic Partnership (TEP), adopted at the EU-US London Summit of May 1998. The TEP is a bilateral agreement to discuss key transatlantic issues ranging from, for example, market access barriers in goods and services to environment and competition law. It is non-binding and focused largely on the integration of commercial or economic issues. In the US, the relevant agencies are USTR, USDA, FDA and EPA (Chapter 6.1). In the EU they are DGs I (Foreign Affairs: Trade), III (Industry), VI (Agriculture), XI (Environment) and XXIV (Consumer) (Chapter 7). Under the agreement, the US and EU are committed to bi-annual political summits supported by more frequent cabinet-level meetings. Then the TEP Steering Group monitors the daily efforts of the TEP sectoral consultations. However, the TEP is only a framework agreement, it is not a legally binding commitment for the US or the EU. It has been argued that this administrative approach has been proposed because dealing with transatlantic issues in isolation does not create the political momentum to move forward (Zampetti, In Press). Focusing on tensions in isolation only serves to highlight failures, not successes. However, as already discussed, given the populist nature of GM crops, trade issues cannot be dealt with in the traditional trade diplomacy framework. Therefore, although linking issues into a progressive convergence strategy is important, it remains crucial that the strategy meets the public demands for open and non-technical dialogue.

The TEP is focused on specific transatlantic market access issues rather than the broader integration agenda of both the treaty and the NTA proposals or the comprehensive trade agenda of the TAFTA proposal, which has very little support within both regions. Instead, it is meant to provide global leadership in agenda setting for the upcoming round of multilateral trade negotiations. Efforts involve identifying shared objectives and priority areas, establishing regular dialogue, and improving co-operation among scientists, regulators and all relevant stakeholders in order to enhance regulatory co-operation. The TEP is also an attempt to increase participation

in trade policy for domestic interests such as consumer and environmental organisations who have long felt left out of the discussions. In this sense, the TEP is an ex ante regulatory co-ordination approach to increased convergence focused on the removal of barriers through mutual recognition.

An identified area of bilateral action under the TEP is agricultural issues associated with biotechnology (TEP, 1998). Both the EU and the US support the need for studying the regulatory structural market access barriers to agricultural biotechnology products within the auspices of the TEP (Wigan, 1998; Schwarz, 1999). It is claimed that the trade friction is related to regulatory processes and is exacerbated by the fact that the dialogue takes place in several different fora. The identified objective is to establish a transatlantic group with a two-fold mandate:

- *to monitor progress of the dialogue on the various technical issues carried out in existing groups, and to take into account their potential trade effects with the objective of reducing unnecessary barriers to trade;*
- *to seek to increase and enhance scientific and regulatory cooperation and information exchange and promote transparency and information to consumers (TEP Action Plan: 14).*

Further, it is recommended that the regulatory divergence be studied through a pilot project that monitors the results of simultaneous applications for scientific assessments in the EU and in the US. Although the target date for this project was the end of 1998, and the sectoral consultation group met in February 1999, there has not been much accomplished at the TEP perhaps because of the current agricultural trade conflict associated with EU market access for hormone-treated North American beef and beef products.

Another relevant area of bilateral discussion under the TEP is the Environment Group. The objective of this group is to negotiate a strategy for dealing with the relationship between trade agreements and environmental agreements; currently an important issue at the WTO's Committee on Trade and the Environment. The Environment Group has five objectives: to identify common US –EU positions to simultaneously pursue at the international level; to enhance scientific and regulatory co-operation; to improve the horizontal co-ordination of environmental issues with other sectoral discussions; to identify common methods for developing multilateral environmental agreements; and to improve co-ordination with and participation of the TAED.

Therefore, the TEP approach is one of technical, low-politics consultations among technocrats. There are two problems with this approach. First, according to Frost (1998) regulatory integration needs a high-level political push. Yet, transatlantic economic relations in the past decade have steadily shifted from 'high politics' to 'low politics'. As high politics, national economic interests were subordinate to the larger strategic aims. Now, transatlantic economic relations are decoupled from the strategic aims and do not have the same political encouragement for integration. A trade war tends to elevate transatlantic economic relations to high politics, but generally not in a beneficial way. Disputing countries become adversaries, not partners, and the final outcome is a zero-sum game of forced convergence, which creates winners and losers rather than mutual beneficiaries. It has been noted that, given the market access difficulties faced by Monsanto in gaining approval for a GM variety of maize, the Clinton Administration has put pressure on the British government to approve this variety (Independent of Sunday, 5 September. 1999). Such an application of 'high political' pressure is not constructive to neither transatlantic economic relations nor to the objective assessment of the safety of GM crops, and it should always be avoided. Second, populist issues are not congruent with traditional trade diplomacy. Without transparency and broader participation, a sceptical public will dismiss any technical regulatory integration decisions as insufficient. Regulatory integration must proceed within a context of national competitiveness on the one hand, and populist concerns and fears on the other.

B. Depth of Integration

Given the dominance of the transatlantic level in dealing with social regulatory barriers to GM crops, the next integration parameter is identifying the appropriate depth of regulatory integration. This is, essentially, a conflict between shallow economic integration and deeper social integration.

The discussion of the development of GM crop regulations has revealed that social interests have played a fundamental role in the regulatory development process. The implication of this is that the integration must be deep enough to address the social issues and concerns driving the regulatory approaches. In other words, social rationality matters and in dealing with social regulatory barriers to GM crops trade diplomacy cannot sustain the traditional divide between economic and social integration. Instead, it must endeavour to include crucial social interests fully in the

trade negotiations. Failure to go 'deeper' immediately anatagonises social interests, and undermines the domestic support for integration through trade agreements.

C. Strategy of Integration

Once the integration level and depth are determined, is crucial to identify the relevant strategy. Recall the choices are essentially between regulatory competition and regulatory co-ordination. The discussion on the traditional trade approach has revealed significant social concerns with the traditional trade approach of regulatory competition, favouring instead a regulatory co-ordination approach.

There are two types of regulatory co-ordination strategies to consider; harmonisation and mutual recognition. Harmonisation represents deep integration as it ultimately leads to the establishment of identical regulations in different sovereign states. Under this co-ordination strategy, national regulatory differences are systematically adjusted to be congruent with regulatory approaches in other states (Wiegele, 1991). Harmonisation has several benefits. First, from an economic perspective it can eliminate market fragmentation based on divergent regulatory approaches, and in essence, level the playing field. Of course, reduced market access difficulties would reduce trade tensions and enhance economies of scale. Second, from a social perspective, harmonisation is congruent with addressing regulatory externalities such as food safety and environmental protection.

There are, however, crucial limits to the harmonisation of national regulations because of important subsidiarity forces. Harmonisation requires national regulatory compromise. From an economic perspective, the potential for agricultural biotechnology in determining future national comparative advantage pressures authorities to retain full control over regulations. Proposed regulatory compromises might not be in the interest of national competitiveness. Indeed, this is exacerbated by the current North American commercialisation lead in agricultural biotechnology over Europe. From a social perspective, regulatory compromise might contradict with domestic consumer or environmental protection concerns. Indeed, it would be unwise for the national governments to concede regulatory authority or compromise in politically sensitive jurisdictions such as consumer and environmental protection.

Additionally, from an institutional perspective, since agricultural biotechnology is a horizontal issue, many domestic government departments and agencies have a regulatory role to play. There are two complications associated with

this. First, securing a package of harmonised regulations across these national regulatory jurisdictions would be difficult let alone the complications of then harmonising the regulations with another state. Second, in an era of government downsizing and streamlining, departments and agencies may be unwilling to concede regulatory authority over portfolios that carry political weight. Therefore, transatlantic regulatory co-ordination must recognise that crucial subsidiarity forces drastically limit the efficacy of harmonisation as an appropriate co-ordination strategy.

The second type of regulatory co-ordination strategy is mutual recognition. This strategy allows for divergence in regulatory approaches and does not pursue the same depth of integration. For instance, states can recognise the hypothetical risk assessment of other states, but then conduct their own risk management procedure. Regulatory co-ordination is achieved when states agree that although their regulatory approaches differ the approaches achieve equivalent outcomes. Mutual recognition limits the need for regulatory compromise.

Yet mutual recognition has some limitations as well. First, it is limited when regulatory divergence is significant because equivalency requires at least some degree of similarity in approach. It has been argued that where there are serious disagreements about Risk Analysis even identifying basic shared objectives is difficult, jeopardising integration (Gatsios and Holmes, 1998). Indeed, it has been revealed that the fundamental regulatory principles have not been established making equivalency at even a minimum level extremely difficult. Second, mutual recognition may fail to address regulatory externalities such as consumer and environmental protection. Two states may mutually recognise their respective approaches, yet either approach may not address the externalities.

Given the benefits and limitations of both harmonisation and mutual recognition, it may be asked; what type of co-ordination can result in regulatory integration that addresses regulatory externalities while simultaneously remaining compliant with powerful subsidiarity forces?

The literature on European integration has dealt extensively with regulatory co-ordination among national governments unwilling or incapable of harmonising regulations. To overcome this problem, a European 'new approach' to regulatory co-ordination has been adopted (Woolcock, 1996). The new approach is the result of a 1985 White Paper on the Internal Market (European Commission, 1985). It was proposed that "harmonisation could be accelerated if the European Council withdrew

from the details of regulation". Instead, the Council would agree to a framework and the relevant service of the European Commission would develop the regulatory approach. It was decided that beyond essential minimum requirements, 'politics' produces bad regulations because it complicates regulatory development. The irony of this, of course, is that European development of GM crop regulations has attempted to reintroduce politics into regulatory development both within Europe (discussed further in Chapter 7) and within international institutions.

Under the new approach essential minimum requirement (EMRs) are established for a particular regulatory issue. These are set at an acceptable level of oversight, creating a regulatory floor and preventing a regulatory race to the bottom. The EMRs are set either by the Council of Ministers or by the European Court of Justice. At the level of EMRs, some degree of harmonisation is necessary (Majone, 1993). EMRs are inherently normative issues of acceptable social objectives setting the regulatory parameteres. On top of the EMRs is a co-ordination strategy of mutual recognition.

Is the new approach to European regulatory co-ordination an appropriate approach for the transatlantic regulatory co-ordination of agricultural biotechnology? Perhaps, but there remain significant challenges. Unlike the European example, where countries broadly agreed upon the minimum public interest, the problem with agricultural biotechnology is the harmonisation of essential minimum requirements. There is significant difference in the respective transatlantic positions on the framework debates, let alone the specific debates. Also, in the case of transatlantic trade, there is no court of justice or council of ministers to impose EMRs if none can be established.

In order to identify the appropriate transatlantic regulatory co-ordination strategies for GM crops, it is necessary to understand the domestic political economy factors of the North American and the EU regulatory approaches in order to characterise the regulatory approaches according the framework and specific regulatory debates discussed above. Chapters 6 and 7 in Part III examine the North American and the EU regulatory approaches to GM crops, respectively.

5.4 Conclusions

In Part II, Chapters 3, 4 and 5, the conceptual framework for analysing social regulatory barriers to GM crops has been developed. The crucial conclusion is that the

regulatory approach, which is a function of endogenous political economy factors, determines the prospects for regulatory integration. Economic and social interests support divergent regulatory trajectories characterised by seven framework debates and five specific regulatory debates. Indeed, a unique feature of GM crop regulations is that even fundamental regulatory principles have not been established resulting is significant regulatory instability.

The instability of the regulatory development process hinders the potential for regulatory integration. Economic interests support the international economic integration approach of scientific rationality exemplified by the international trade regime. Social interests support the international social integration approach. Due to this conflict, there is no obvious international institution, including to the WTO, to achieve regulatory stability and integration. Instead, the most important level of regulatory integration is the transatlantic level where the integration must be capable of meeting the social aspects of domestic regulations.

PART III TRANSATLANTIC REGULATORY REGIONALISM

The objective of Part III is to examine the transatlantic regulatory regionalism associated with the development and commercialisation of GM crops in order to identify the prospects and limitations for regulatory integration.

Both the North American and the European regulatory approaches are based on the Risk Analysis framework. In fact, until 1990 they were on the same regulatory trajectory with largely congruent positions on the regulatory principles reflecting a scientific rationality paradigm. By 1990, however, endogenous political economy factors resulted in a shift of EU regulation away from this common trajectory and towards a significantly divergent framework more closely reflecting the social rationality paradigm.

The result has been the creation of transatlantic regulatory regionalism and regulatory market access barriers facing GM crops. Essentially, GM varieties of agricultural crops approved in North American marketplace have not gained similar approval in the EU. Instead, applications have faced significant regulatory hold-up and rejection. For example, a GM variety of flaxseed, CDC Triffid, approved for commercial release in Canada, has not been approved nor rejected in Europe. Since 1997 the application remains in regulatory limbo. This has created trade tensions because about 90% of Canadian flax is exported and the EU is the largest export destination. Although approved in Canada, Canadian producers and distributors voluntarily refused to commercially plant the GM variety because without an EU accepted identity preservation production (IPP) system, exports to the EU could not be guaranteed as free of the GM variety and all Canadian flax exports would be banned. In fact, this is exactly what has happened to Canadian canola exports and US corn exports to the EU in the period 1997 – 99. In Canada, a total of seven GM varieties of canola have been approved for commercial release and are widely planted. Yet, only four of the seven have been approved in the EU, while the remaining three applications are held-up in the EU's regulatory approval system (discussed in Chapter 7). Without an IPP system, segregation of the approved from the non-approved varieties cannot be ensured nor can segregation of GM from non-GM varieties. As a result, Canadian exports of canola to the EU have fallen dramatically. In the US, it has been estimated by the US Department of Agriculture that EU regulatory hold-up has resulted in over $US 200 million in lost corn sales.

In order to understand the divergent regulatory approaches, each jurisdiction must be characterised according to its competitive position and its regulatory features. With respect to the former, the current capacity must be assessed along with efforts in the jurisdiction to promote the development and commercialisation of GM crops. With respect to the latter – the jurisdiction's regulatory features – several aspects must be characterised including the traditional regulatory role of the state, the interests involved in regulatory development, the structure of the regulatory regime along with an assessment of the stability of the approach and a forecast of the trajectory. The North American regulatory approach will be characterised in Chapter 6 while the European approach will be characterised in Chapter 7.

CHAPTER SIX NORTH AMERICAN REGULATORY APPROACH

6.1 Introduction

The North American regulatory approach is employed in Canada and the United States although similar approaches may be found in Australia, Mexico and Japan. The objective of this chapter is to characterise the North American regulatory approach to agricultural biotechnology products by examining its development in the United States and in Canada. This includes identifying the public initiatives to promote biotechnology as well as the efforts to regulate agricultural biotechnology. In this chapter is also an examination of the degree of Canada – US regulatory integration made possible because of the similarities in regulatory approach.

Prior to discussing the North American approach to regulating GM crops, it is useful to understand the social context of agricultural production. Unlike in many parts of Europe, agricultural land is not also 'wilderness', so the emotive consumer concerns associated with environmental biodiversity are not focused on agricultural production land. In this sense, the North American agricultural sector is primarily an industry for making food stuffs and does not double as the protector of the wilderness as in Europe. This is not to say, however, that North American agricultural producers are not themselves concerned with the environmental impact of their activities, and indeed, many take great efforts to adopt sustainable practices. It is only to suggest that the broader public does not envisage a special 'multifunctionality' role for the farming community to the extent found in Western Europe (to be discussed in Chapter 7.1).

6.2 Agricultural Biotechnology in the United States

The United States is the global leader in biotechnology capacity in general, and is the dominant country in agricultural biotechnology in particular (OTA, 1991). In essence, the US experience with biotechnology has significantly influenced the promotion and regulation of biotechnology in the rest of the world.

6.2.1 US Promotion of Agricultural Biotechnology

The global dominance of the US in biotechnology capacity has occurred without strategic industrial targeting programs. It is argued that the US has lacked, and indeed continues to lack a comprehensive industrial development strategy aimed at building biotechnology capacity (Wiegele, 1991). Instead, public policies are more

broadly targeted at the development of all industrial initiatives employing knowledge-based, innovative, advanced technologies. Public funding through the federal government is available to assist basic, non-commercial research in these areas in collaboration with universities, research institutes and private companies. Funding for commercially oriented research is generally left to the financial market. Lavoie and Sheldon (1999) have argued that the US regulatory framework has had more to do with the private sector led, commercialisation of agricultural biotechnology products than any commercial public policies of industrial targeting. In 1991, the President's Council on Competitiveness recommended two key principles of US biotechnology regulations. The first was a focus on product standards rather than technology or process standards while the second was to regulate under existing vertical or sectoral regulatory departments. The importance of these recommendations is that the regulatory approach was linked explicitly to the competitiveness of US biotechnology. Further, as will be noted below, they established explicit support for a scientific rationality trajectory of US biotechnology regulations.

On 30 November 1999, the US-based Alliance for Better Foods held a news conference in Seattle, Washington to outline US support for agricultural biotechnology and for the US regulatory system. Supporters included US senators and congressmen, industry participants as well as leading international scientists. Most notable was as statement of support for agricultural biotechnology and GM crops and the US regulatory approach under-signed by 330 scientists (AgraFood Biotech No. 20, 1999).

Other organisations involved in the promotion of US biotechnology include the: Industrial Biotechnology Association (IBA); Association of Biotechnology Companies (ABC); American Society for Biotechnology (ASB); Biotechnology Industry Organisation (BIO); Grocery Manufacturers of America; American Farm Bureau Federation; National Grain and Feed Association; Food Distributors International; International Food Information Council; National Food Processors Information; and the American Feed Industry Association. An important common link between these organisations is widespread support for the regulatory framework that has been adopted in the US, as opposed to framework adopted in the EU.

In short, the US enjoys a substantial commercialisation lead in agricultural biotechnology, especially over the EU (James, 1999).

6.2.2 The US Regulatory System

Due primarily to the global capacity lead, the US has led the rest of the world in developing a regulatory base for biotechnology products. The initial regulatory approach was driven by scientists many years before there were any market-ready commercialisations of biotechnology-based products. It was based upon the desire of these scientists to proceed with caution in genetic modification techniques.

With respect to the traditional US regulatory role, it has been argued that regulatory intervention in follows a regulatory independence approach (Majone, 1990). Congruent with the economic perspective, the regulatory independence approach prescribes government regulatory intervention only in reaction to market failure[1] where regulations seek to ensure market efficiency or effectiveness rather than replace the market. In this sense, the market decides the effectiveness of regulations, not regulators. Indeed, with respect to modern biotechnology, it is quite appropriate to suggest that US regulations have been pro-competitive, and focused on removing market failure to enhance market efficiency and effectiveness.

This traditional regulatory role has been congruent with the development of a scientific rationality approach to US biotechnology regulations. In June 1973, the Gordon Conference on Nucleic Acids recommended that the life science participants send a letter "to the US National Academy of Sciences and the US Institutes of Medicine calling attention to possible biohazards from new viral strains emerging from laboratory research" (Wiegele, 1991). In response, the National Academy of Sciences and the Assembly of Life Sciences of the US National Research Council appointed a panel of scientists to examine the biohazard concern raised by the Gordon Conference participants. The ensuing report recognised that there is a potential risk (either a hypothetical or speculative), rather than a recognisable risk from biotechnology, but nevertheless encouraged a voluntary moratorium on some types of experiments until the international scientific community could discuss the risks (Berg *et al.*, 1974). This recommendation appears to indicate that the initial interpretation of the precautionary principle on the part of the world's leading scientists was the

[1] Market Failure: "The inability of a system of private markets to provide certain goods either at all or at the most desirable or 'optimal' level...The existence of market failure is usually held to provide a case for collective or government action to improve allocative efficiency" Pearce (1996).

scientific interpretation because 'precaution' was linked to the gathering of further scientific risk information.

Following the report's recommendations, in February 1975 the National Academy of Sciences convened the *International Conference on Recombinant DNA*, known as the Asilomar Conference in Pacific Grove, California. The Asilomar conference focused on two points. First, was how to minimise 'potential' risk, and second, how to appropriately involve the public. With respect to minimising the risk, the participants agreed on the establishment of a two-stage graduated scale for assessing risks: low risk and high risk. It has been argued that the low risks were hypothetical risks while the high risks were speculative risks (van den Daele, 1997). With respect to involving the public, the participants recognised both the presence of a significant information gap and the adverse effects undue public fears could have on important and vital research. Therefore, conference recommendations were keen to establish guidelines that the public would consider appropriate and acceptable. Essentially, although the guidelines were established to deal with hypothetical risks, there was awareness that speculative risks (i.e. high risks) could be the basis for concerns and fears that would, in turn, jeopardise research efforts. In this sense, the scientific community recognised that speculative risks could not be ignored.

The Recombinant DNA Advisory Committee (RAC), established in 1975 by the National Institutes of Health (NIH), played an influential role in setting guidelines and recommendations for research using genetic modification techniques (Ager, 1990). In 1976 the National Institutes of Health issued the first guidelines related to rDNA research, the 'National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules'. These guidelines were only focused on controlled research not on experimental or commercial environmental release. There were two important aspects of the guidelines. First, it was argued that there was no significant risk inherent in the use of biotechnology requiring technology-based regulations. Second, it was recommended that the degree of regulatory oversight should vary based on both the degree of research containment and on the scientifically determined hypothetical risk. The guidelines reflected a commitment to both the principle of 'substantial equivalence' and the scientific interpretation of the precautionary principle. This provided the base for the US regulatory structure.

Within five years of the Asilomar Conference and the NIH guidelines, most scientists had reassessed their initial judgements about the safety hazards of rDNA

research because of continued experimentation and accumulating risk information. As a result, there was substantial support for a relaxation of the guidelines in light of this information (Ager, 1990; Wiegele, 1991). This indicates a discernible shift from hypothetical risks to recognisable risks made possible by the scientific interpretation of the precautionary principle. Although imposing initially restrictive, precautionary guidelines, it allowed for the R&D necessary to better understand the hypothetical risks, which in turn led to a relaxation of the guidelines, based on known or recognised risks, in turn fostering further research and development and the accumulation of risk information.

In 1983, the National Academy of Sciences of the National Research Council published the 'Redbook' on regulating the risks of advanced technologies (NAS, 1983). The important aspect of this publication was that it set out a new regulatory paradigm based on the concept of Risk Analysis. This paradigm significantly shaped the US regulatory approach to modern biotechnology (Mackenzie, 1993). The Redbook identified the now familiar Risk Analysis trilogy of risk assessment, risk management and risk communication (see Chapter 5.1).

With the growth of research and development in agricultural biotechnology, pressure began to mount for guidelines to deal with imminent environmental release of genetically modified organisms (GMOs). There were two guidelines that responded to this pressure. In 1985, a co-ordinating committee, the Biotechnology Science Coordination Committee (BSCC) was established by the President's Office of Science and Technology Policy (OSTP) and staffed by senior academic and industry scientists (Wiegele, 1991). The BSCC, through the OSTP published the first guideline to deal with environmental release, the 'Co-ordinated Framework for Regulation of Biotechnology' (OSTP, 1986). The second guideline was the National Research Council's 'Field Testing Genetically Modified Organisms: Framework for Decisions'. These guidelines were very similar and they both concluded that although some biotechnology applications would create novel products with novel hazards, other applications would not. With respect to GM crops it was concluded that the hazards or risks from GM crops were substantially equivalent to the hazards from conventional varieties or, in other words, some GM crops are substantially equivalent. Both guidelines supported the application-basis of the scientific rationality paradigm by suggesting that there was no significant risks inherent in the application of biotechnology per se, hence, they did not support new technology or process-based

regulations. It has been argued, however, that these conclusions should not be interpreted as suggesting that GM crops are not different from non-GM crops, indeed they are different, but not in the risk or hazard that they pose (Mackenzie, 1993). Instead, both guidelines suggested that additional regulations for GM crops combined with inter-agency co-ordination were necessary, but as part of the existing vertical regulatory oversight.

In 1990, the BSCC was replaced by the Biotechnology Research Subcommittee, and indication of the 'permanence' of the biotechnology issue on the US industrial landscape. Further, in 1991, the President's Council on Competitiveness recommended two key principles of US biotechnology regulations. To focus on product standards and to regulate under vertical or sectoral existing regulations. These principles were viewed as necessary to ensure the safety of biotechnology-based products while simultaneously enhancing the competitiveness and commercialisation lead of the US biotechnology industries.

Clearly, since 1973, US biotechnology regulations have been on a scientific rationality trajectory employing safety or hazard-based definitions of risk, the substantial equivalence principle and the traditional burden of the proof. The result has been a product or application-based regulatory approach under the jurisdiction of existing, vertical departments and agencies and employing the scientific interpretation of the precautionary principle.

Three agencies currently share responsibility for the regulation of GM crops. The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) is responsible for environmental assessments of plant risk, issuing permits for field testing (Environmental Use Permits or EUPs), and for regulating the importation and interstate movement of genetically modified plants. USDA's APHIS examines all organisms and products altered or produced through genetic engineering that are or have the potential to be plant pests. The APHIS regulatory procedures have been simplified twice. In 1993, six GM varieties were 'delisted' meaning that they only required notification for field-testing, not an Environmental Use Permit. This action was based on the confidence of accumulated field trial experience in the US. Under the second simplification, adopted to speed the application review, APHIS regulations provide for a petition process where the proponent can request their product be granted a non-regulated status. The proponent submits the necessary evidence to prove that the GM plant does not pose a plant pest

risk. APHIS reviews the evidence, and if approved, the plant product (and all its offspring) no longer requires APHIS review for interstate movement or environmental release in the US. The necessary evidence involves a scientific risk assessment.

The US Environmental Protection Agency (EPA) is responsible for the environmental release of both bio-engineered pesticides and bio-engineered plants with pesticidal characteristics, such as Bt-corn and Bt-cotton varieties. Novel GM crops with pesticidal characteristics are subject to EPA assessments considering the impacts upon the target organisms, non-target organisms including humans. For instance, the main impact on GM varieties of herbicide resistant crops is the requirement that the EPA establish tolerances for residues of herbicides used on GM herbicide-tolerant crops. It has been argued that the Toxic Substances Control Act (TCSA), administered by the EPA, explicitly employs the scientific interpretation of the precautionary principle since, "the language of the statute express Congress's clear intent that research and development activities involving small amounts of substances be exempt from regulation"(Rogers, 1990). In late 1999, the EPA's Ecological Effects Team announced that "companies developing GM crops will face changes in testing requirements over the coming years" (AgraFood Biotech No. 20, 1999). This reflects two trends. First, the increase in novel applications in GM crops necessitates new testing requirements including more comprehensive scrutiny. Second, the growth in a predictive ecology framework for risk assessment methods will better guide regulators to improve the accuracy and acceptability of environmental risk assessments. In other words, these changes must not be interpreted as a dramatic u-turn in EPA policy, instead, they are simply the natural evolution of regulations as GM crops move from production trait varieties to both output improved varieties and bio-engineered commodities and as regulators gain more data on recognised risks.

The third institutional arrangement in the US regulatory system is the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS). The FDA has traditional responsibility over ensuring the safety of food and feed use crops. It is important to note that FDA consultation is not mandatory but recommended prior to the market release of genetically modified foods and feeds. According to a 1992 FDA Statement, the focus of FDA oversight is on the novelty of food plants, not on the use of biotechnology per se (FDA, 1992). In fact, biotechnology-based products only come under direct FDA jurisdiction if they are determined to be a food additive according to the authority of the Federal Food, Drug,

and Cosmetic Act. The 1992 Statement concluded, however, that the transferred genes are not additives because there is no a priori reason to conclude that transferred genetic material would create new hazards not present with conventional products (Koster and Balf, 1998). Accordingly, the FDA regulates the use of biotechnology under the substantial equivalence principle; only if it is from a novel plant significantly different in structure, function, or composition from plants currently used in food products. Many of the GM crops currently being developed for food use do not contain substances that are significantly different from those already in the diet and thus do not require FDA's pre-market approval.

It is important to note that while FDA consultation is voluntary, there have been no GM products approved for commercial use that have not gone through FDA consultation. Simply, industry recognises the important confidence boost that an FDA endorsement gives to products. Also, FDA consultation is *de facto* standard because of US product liability laws. From the firm's perspective, commercial risk is minimised and consequently food safety risk is minimised through FDA consultation which in turn limits liability risk. Many GM supporters, however, recognise that the FDA consultation is vulnerable to attack by critics because of the fact it is voluntary, despite the reality that the consultation is *de facto* standard. This has led some to argue that as the consultation occurs anyway, it would be useful from a public concern perspective to formalise the pre-market consultation in order to stem the potential criticisms[2].

There is a horizontal regulation in the US with oversight for environmental issues hence, it is relevant for GM crops. The National Environmental Protection Act (NEPA) requires that all departments and agencies must perform an adequate environmental assessment on all activities falling under their jurisdiction that will have an impact upon the environment. With respect to agricultural biotechnology, this includes all deliberate releases for the field-testing or commercial planting of GM varieties. The US federal regulatory approach is presented in Table 6.1 below.

There also exists state-level regulatory oversight in the US (Rogers, 1990). Before commercialisation, GM plants must also conform with standards set by State and Federal marketing statutes such as State seed certification laws but there are no

[2] Jeffrey Barach, National Food Processors Association (1999) Comments at the FDA Public Consultation of Agricultural Biotechnology in Washington DC, 30 November 1999 in AgraFood

national requirements for varietal registration of new crops. One issue that has arisen at various times and in certain places is the potential for States and local governments to enact their own laws to address environmental concerns. Several states have enacted legislation regulating field trials requiring either notification of the release of GM varieties (Hawaii, Illinois, Wisconsin) or requiring formal permits for trials (Minnesota and North Carolina). Nevertheless, once the product has been approved for unconfined release at the federal level, the individual States lose regulatory oversight and cannot prohibit the unconfined release of GM crops.

Agency	Products Regulated	Additional Info.
U.S. Department of Agriculture (APHIS)	Plant pests, plants, veterinary biologics	Federal Plant Pest Act - 7 USC 7B
Environmental Protection Agency	Microbial/plant pesticides, new uses of existing pesticides, novel microorganisms	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - 7 USC 136 Federal Food, Drug, and Cosmetic Act (FFDCA) - 21 USC 9 Toxic Substances Control Act (TSCA) - 15 USC 53
Food and Drug Administration	Food (except meat, poultry, and egg products), feed, food additives, veterinary drugs	GRAS status Federal Food, Drug, and Cosmetic Act (FFDCA) - 21 USC 9 Statement of Policy: Foods Derived from New Plant Varieties
Horizontal Legislation		
National Environmental Protection Act (NEPA)	Requires all actions, which will have an environmental impact, to be subject to an adequate environmental risk assessment by the relevant regulatory agency.	

Table 6.1 US Agricultural Biotechnology Regulations

The regulatory decision-making process according to the US approach may be characterised as having narrow participation in the process. Under the hypothetical risk assessment the 'experts' are left to perform the assessments where the experts are either federal regulators or the risk assessment personnel of the proponent GM crop developer. Under the risk management procedures, the decision-making is made within the relevant vertical regulatory jurisdictions. It has been argued that the decision-making power rests with "a small cadre of scientists, venture capitalists and government bureaucrats, most of whom have a vested interest in the growth of the genetic engineering industry..." (Rogers, 1990). Yet, on the contrary, others have argued that despite the limited participation in the decision-making procedures, there

Biotech (1999) 'FDA Closer to a New GM-Free Foods Label Policy' No. 19, 8 December 1999 (London: AgraEurope Ltd.).

is considerable opportunity for public comment on the draft policies at both the risk assessment and risk management stages (Fuchs, 1993). In fact, in 1992, each of the three regulatory agencies, APHIS, FDA and EPA, all published draft regulatory guidelines for public comment[3].

An added dimension to US regulatory development is the regulatory evaluation by the Office of Management and Budget (OMB). The OMB assesses proposed US regulations and legislation to ensure that new regulations will generate the desired outcome while limiting the political influence behind them. The OMB evaluations actually support a scientific rationality approach to regulating advanced technologies. In fact, the OMB approach does not support engaging all stakeholders in the risk management process because such involvement can potentially distort regulatory development beyond the goal of market failure correction (Belzer, 1998). OMB's regulatory evaluation framework is composed of four objectives. First, to identify the market failure used to justify the intervention. Second, to analyse the impact of the identified market failure to determine both its presence and its significance in distorting market outcomes (e.g. impact on competition, equity, employment, public health, etc). Third, to analyse existing federal regulations and legislation to determine whether amendments to existing frameworks are capable of addressing the identified market failure. Fourth, to analyse all regulatory alternatives in order to determine the optimal regulatory approach. With respect to the Risk Analysis framework, the OMB evaluation supports risk assessment based on hypothetical risks, focused on safety or hazards only as well as risk management limited only to the goal of reducing or preventing risk, not the goal of assuaging public fears and concerns.

The US Regulatory system is subject to an independent scientific review by the National Academy of Sciences in 2000 and 2001. A major focus of this review is not on human health, but on the "environmental impacts associated with commercialisation of biotechnology derived plants and to provide guidance on how best to assess and mitigate risks" (World Food Law Monthly No. 19, 1999). The focus

[3] APHIS: Animal and Plant Health Inspection Service (1992) 'Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Non-Regulated Status' (Washington DC; Federal Register Draft Guidelines 12 June 1992 57:40632 and Final Policy March 1993 58:17044); EPA: Environmental Protection Agency (1992) 'EPA Proposal to Clarify the Regulatory Status of Plant Pesticides' (Washington DC; Federal Register 57:55531); FDA: Food and Drug Administration (1992) 'Statement of Policy: Foods Derived From New Plant Varieties' (Washington DC; Federal Register 29 May 1992 57:22984)

on the environmental impacts is a direct effort to address the speculative risks raised by critics through a science-based analytical approach to environmental risk assessment.

The mandatory labelling of GM crops and foods produced from GM crops in the US has been influenced by the regulatory development assessed above. For instance, the determination of substantial equivalence along with the FDA's 1992 decision that GM material in itself is not an additive do not support the consumers' right to know justification for labelling. It has been argued that the traditional justification for mandatory labelling is for hazard warning, not for the consumers' right to know (Korwek, 1993). Further, it has been argued that US case law reveals that "consumer interest alone is not enough" for mandatory labelling and that a production method that has no discernible impact on the safety or quality of a final product is not a sufficient justification either (Koster and Balf, 1993). The FDA policy on labelling irradiated meat products was however a mandatory labelling policy justified by the consumer's right to know. The key to this decision is found under the labelling section of the Federal Foods, Drugs and Cosmetics Act (FFDCA) Section 403(a)1 which requires that mandatory labelling must reveal 'material facts' in order to prevent misbranding. Irradiation, as a production method was considered to be a material fact (Koster and Balf, 1993).

What is the difference between irradiation technology and GM technology? It appears that GM technology which is used in the seed development and not in the crop production and the food processing stages escapes this context of material facts. If GM technology was applied while crops were growing or when they were being processed, than this would be a material production fact that consumers would have a right to know about. Instead, because of the substantial equivalence principle, GM crops are slotted into the same production and processing system as same-use non-GM crops and there are no material differences in the processing procedures.

There is currently considerable pressure on the FDA's position on mandatory labelling. For instance, the FDA's policy on substantial equivalence is under legal challenge by the US-based International Centre for Technology Assessment (ICTA), a non-governmental organisation that monitors the social implications of technological innovations (Economist, 19 June 1999). There are two important aspects of this challenge. First, the ICTA wants the FDA policy on GM material altered so that GM material is considered to be an additive and therefore subject to FDA pre-market

approval. Second, the ICTA wants a mandatory US labelling policy on foods produced from GM crops according to the consumer's right to know. The outcome of this challenge is currently unknown. Also, Democrat Representative (Ohio) Dennis Kucinich presented a bill to Congress calling for mandatory labelling of GM Foods based on the consumer's right to know and requiring a 0.1% level of adventitious contamination. As a result of these pressures, as well as the broader public concern, especially in Europe, the FDA is consulting with the public on its labelling policy. This is an important development because the FDA recognises the need for regulations to move beyond just scientific parameters and to assuage public fears in order to prevent a collapse in consumer confidence. The outcome of these consultations is likely to be that the FDA will not adopt a mandatory labelling policy based on the consumer's right to know and instead it will develop legal standards for using a voluntary GM-Free label.

With respect to the international integration of biotechnology regulations, the US is involved in bilateral and multilateral negotiations for both the development of an international regulatory approach and for the enhancement of regulatory convergence between countries. Bilateral efforts include those taken under the North American Free Trade Agreement and those under the Transatlantic Economic Partnership. Multilateral efforts include US involvement in the establishment of Codex Alimentarius food safety standards and the various committees administering World Trade Organization Agreements. In 1996, the Clinton administration published a report on the desired future for US food regulations (Clinton and Gore, 1996). Among other things, this report identified, as a priority, efforts by US regulatory agencies to promote the international harmonisation of food regulations. As a result, agricultural trade policy, developed by the relevant agencies (FDA, EPA, FSIS and APHIS of USDA) is concerned with the presence of technical barriers to trade in US food stuffs in order to address the concerns of US exporters. For instance, the Foreign Agricultural Service (FAS) of the USDA attempts to identify trade barriers and to challenge their use through consultation in international fora including the TBT and SPS Committees. Public participation in trade policy development is through the Advisory Committee on Trade Policy Negotiations. When trade concerns become trade tensions, the US Office of the Trade Representative (USTR) takes over. The USTR seeks to consult on the reduction or removal of trade barriers and acts as the relevant US agency in the event that trade disputes under international agreements

arise. The US also has legislation to act unilaterally to address perceived unfair trade practices of other countries, outside the scope of international agreements. According to Section 301 of the US Trade Act of 1974, the Department of Commerce can take action against the imports of foreign goods in response to "unfair and discriminatory practices or breaches of trade agreements" by trading partners (Horton, 1997). This unilateral action is controversial and many trading partners feel that it undermines the rules-based trading regimes outlined in international trade agreements.

The US Regulatory System and regulatory responses cannot be fully characterised without some mention of US Product Liability Laws, briefly mentioned above. These laws confer legal liability on the product manufacturer. That is, in the event of a food or environmental safety incident a consumer only has to show that the manufacturer was responsible for the product, not that the manufacturer was negligent. US Product Liability Laws are an important factor in the internalisation of food and environmental safety risks by US manufacturers because a safety risk quickly becomes a commercial crisis. Firms minimising commercial risks in the US are simultaneously minimising safety risks.

Therefore, the US Regulatory System may be characterised according to the scientific and social rationality paradigms identified in Chapter Five (Table 6.2). The general interpretation of the US regulatory approach is that it is overwhelmingly a scientific rationality approach. Essentially, the US regulatory system is based on the belief that the new techniques of genetic engineering are an extension of traditional breeding techniques and biotechnology-based products are simply an extension of existing product classes (APHIS, 1999). In this sense, regulations have been developed which build on the experience and expertise of and the public confidence in US regulators.

With respect to the five specific regulatory debates associated with GM crops, the US approach employs the scientific interpretation of the precautionary principle. Indeed, there is considerable confidence that over 25 years of scientific assessment has shown that the risks from genetic modifications are not inherently different than the risks from conventional crops. Second, US regulations are focused primarily on novel products of agricultural biotechnology not on agricultural biotechnology as a process or production method. Third, US regulatory authority is under traditional, vertical regulatory jurisdictions based on existing statutes with amendments to deal with novel products. It is held that there is not an appropriate horizontal statutory

approach because of the broad spectrum of applications, and that existing health and safety laws provide immediate regulatory protection based on long-standing expertise. Fourth, because agricultural biotechnology products are considered within existing vertical regulations, participation in decision-making remains largely limited to the traditional actors and decisions are judicious. Fifth, US labelling policies are not currently in support of either mandatory labelling of the GM techniques or mandatory labelling for the consumers' right to know. Instead, mandatory labelling is focused on novelty and safety or hazard justifications only. Although, as noted the US labelling policy is under legal challenge, and the outcome of this challenge is currently unknown.

	Scientific Rationality	Social Rationality
General Regulatory Issues		
Tradition	✓ Regulatory Independence	
Belief	✓ Technological progress: Enhances growth and development leading to higher social regulations – a regulatory race to the top.	
Type of Risk	✓ Recognised ✓ Hypothetical	
Substantial Equivalence	✓ Yes	
Science or Other in Risk Assessment	✓ First regulatory hurdle	
Burden of Proof	✓ Traditional: Minimise Type I (Rejected when safe)	
Risk tolerance	✓ Minimum	
Science or Other in Risk Management	✓ Safety or Hazard-based Risk Management is for risk reduction and prevention only	
Specific Regulatory Issues		
Precautionary Principle	✓ Scientific Interpretation	
Focus	✓ Product-based, Novelty	
Structure	✓ Vertical, Existing structures	
Participation	✓ Narrow, technical experts ✓ Judicial decision-making	
Labelling	✓ Safety or Hazard only Voluntary, market-based for the consumers' right to know	

Table 6.2 US Regulatory Approach Checklist

There are two perspectives from which to view the US Regulatory System; an economic perspective and a social perspective, which includes consumer concerns about food safety, environmental protection along with moral and ethical concerns.

Economic Perspective

From an economic perspective, the US system provides industry with predictable and timely decisions. A GM crop regulatory submission requires three types of information (Kraus, 1998). First, the firm must submit information on the genetic characteristics of the host and recipient organisms, on the vector of transfer employed and on the resultant genetic characteristics of the GM crop. Second, information on the purpose, method of data collection and harvest procedures for the field trial must be submitted. Third, information on the field trial location and the supervision procedures must also be submitted. Once approval has been given on the particular GM crop variety, the only regulatory responsibility is an annual field trial report. This field trial regulatory approach has been commercially friendly. For instance, APHIS received more than 920 requests for the environmental release of GM varieties between 1988 and 1998. Of these requests, 886 were approved. Also, between 1992 and 1999, APHIS received 65 petitions for deregulation, where 49 were approved in an average of four months, while 11 were voluntarily withdrawn and 5 were rejected. The EPA approved 34 proposals for the environmental release of biopesticides between 1987 and 1996. The FDA reviewed and approved the commercial release of 43 GM crops between 1994 and 1998[4].

With respect to regulatory requirements for GM crops for human food use, Fuchs (1993) has detailed the regulatory compliance efforts of Monsanto in seeking approval for the GM potato variety resistant to the Colorado potato beetle (CPB)[5]. The Monsanto strategy was two-fold. First, to establish that the GM potato was substantially equivalent to conventional varieties and, hence, not subject to novelty regulations. This involved comparative testing of the potato's (1) nutritional and natural composition, (2) the level of macro-nutrients (e.g. protein, fat, carbohydrates, dietary fibre), (3) level of vitamins (e.g. C, B_6, Thiamine, Niacin, Folic Acid and Riboflavin) and (4) the level of minerals (e.g. calcium, copper, iron, iodine, magnesium, phosphorus, potassium, sodium, zinc). This comparative testing supported Monsanto's claim of substantial equivalence, except in the category of insect resistance, which of course was the reason for the development of the GM

[4] Regulatory decisions from: Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) March 1999 (www.aphis.usda.gov/oa/new/ab.html).
[5] Fuchs (1993) ...

variety in the first place. The second strategy was to provide required data on human, animal and environmental safety performance of the GM potato.

Of course, US agricultural biotechnology firms favour the predictability and stability of the US regulatory approach because it clarifies the information requirements that firms must meet. This is reflected in high rates of application approvals with few regulatory hold-ups. It has been argued that "the US plant biotechnology industry has been positively affected by domestic regulation and finds itself at a comparative regulatory advantage to its European counterpart" (Kraus, 1998). In short, the US scientific rationality approach to regulating GM crops benefits the economic interests by ensuring a predictable framework encouraging technological progress.

Social Perspective

From the social perspective, it has been argued that the US regulatory agencies, such as the FDA and the EPA, are trusted by the public to protect both the food supply and the environment (Hoban, 1998). It has also been argued that "it is not an overstatement to suggest that the level of scientific research and testing involved in biotechnology [agricultural] is at least as good as that available in the health care field" (Balk, 1993). Indeed, public trust in US medical regulations is high, and capturing that level of trust is a crucial part of establishing socially acceptable regulations. An important concern of US regulatory development was that attempts to develop a new set of horizontal regulatory rules or a new regulatory agency might have undermined the public trust. Kraus (1998) argued that the decision to keep regulatory oversight within the traditional vertical jurisdictions is the reason for increased consumer confidence and public acceptance in the US.

The US approach does, however, have significant shortcomings in dealing with the social dimensions of agricultural biotechnology. For instance, the important role of APHIS may be construed as a conflict of interest since the USDA is playing the dual role of promoting the agricultural sector while at the same time regulating it. This raises concerns about regulatory capture and who are the clients of the USDA; industry or consumers? In fact, other countries such as Canada and the UK have taken steps to separate the promotion and regulation activities into different regulatory

agencies[6]. Further, limited actor participation in the regulatory decision-making process may increase fears that agricultural biotechnology is being approved without adequate public consultation or consent. Indeed, if GM foods become as politicised in the US as they currently are in the UK, the US regulatory system will be under considerable pressure to consider the social dimensions of agricultural biotechnology, yet it may be poorly equipped to do so. The ability to transform the vertical regulatory agencies into a manner sufficient to the interest groups, without changing the underlying regulatory principles on which the system is based, appears very limited.

This threat has been at the heart of proactive, co-ordinated efforts in the US by government and industry to stop any "social contagion" resulting from UK and European consumer reactions (Economist, 19 June 1999). The strategy is to investigate scientific, economic and social concerns through broad participation in advisory committees supported by the National Economic Council and the USDA. As well, the Grocery Manufacturers of America, an industry association, is determined to prevent consumer concerns from forcing product reformulation on its members as happened in the UK. In other words, industry is working in co-ordination with government to protect against potential regulatory instability that could have serious commercial implications.

6.3 Agricultural Biotechnology in Canada

Biotechnology in Canada is considered to be vital to future growth prospects. Although global capacity leadership is enjoyed in several specific areas such as the genetic modification of oilseeds, overall, biotechnology capacity in Canada tends to lag the US as well as Japan and several European countries.

6.3.1 Canadian Promotion of Agricultural Biotechnology

Unlike the US, public policy in Canada directly targets the deepening and widening of the Canadian biotechnology capacity. According to the Canadian Biotechnology Strategy (CBS), the application of biotechnology in the production of agricultural, industrial and medical goods is held to be a potential cornerstone of the economy (Industry Canada, 1997). Further, the Canadian Institute of Biotechnology

[6] In Canada, Agriculture and Agri-Food Canada (AAFC) promotes while the new Canadian Food Inspection Agency (CFIA) and Health Canada (HC) regulates and in the UK the Ministry of

(CIB), argues that "biotechnology is an important driver of economic growth in Canada. It has become an important tool that, when used appropriately, can increase the competitiveness of all sectors from agriculture to health care" (CIB, 1997).

The Canadian federal government, along with some provincial governments have been very proactive in the development and commercial application of modern biotechnology to Canadian products. In 1983, the National Biotechnology Strategy was established committing approximately $C 13 million/year to biotechnology research through National Centres of Research Excellence. It has been estimated that government promotion has averaged $C 250 million/year or over $C 1.5 billion for the decade 1987 – 1997 (CIELAP, 1997).

Industry associations include national associations such as Canadian Institute of Biotechnology (CIB), Industrial Biotechnology Association of Canada (IBAC), Biotechnology Human Resource Council (BHRC), National Biotechnology Network, and Food Biotechnology Communications Network. There are also regional associations in all provinces. In 1996, the IBAC developed a Voluntary Code of Conduct to guide the interactions between industry, government regulators and the broader public.

While Canada does not hold a commercialisation lead in agricultural biotechnologies over the US, it does have a lead over the EU. The result, of course, is a North American commercialisation lead.

6.3.2 The Canadian Regulatory System

In Canada, traditional regulatory role has been primarily influenced by the US, due to the economic importance of the US market to Canadian products, although there has been, of course, some European influence. Indeed, in some respects the Canadian approach blends the regulatory independence approach of the US, with the European regulatory accountability approach. As in the US, the regulatory independence approach prescribes government regulatory intervention only in reaction to market failure. However, unlike in the US, Canadian regulators also examine the 'effectiveness' of regulations. This is more closely associated with the European approach employing the fourth regulatory hurdle (i.e. safety, quality, efficacy and effectiveness or social benefit, see Chapter 5.1.4). Canadian regulatory decision-

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Agriculture, Fisheries and Food (MAFF) promotes while the proposed Food Standards Agency (FSA) will regulate.

making is traditionally done by regulators limiting the influence of populist politics and day-to-day public interests on the regulatory system. Therefore, the traditional Canadian regulatory role, although allowing for the evaluation of social benefit, does hold market correction as the fundamental role of regulatory intervention. Indeed, with respect to modern biotechnology, it is quite appropriate to suggest that Canadian regulations have been pro-competitive.

The Canadian regulatory system for GM crops was driven endogenously by the development of GM canola/rapeseed varieties and exogenously by the rapid pace of R&D and commercialisation of GM crops in the US. In earlier periods the health and safety regulatory system supported and assisted the canola industry to develop and tended to take its lead from the industry (Phillips and Khachatourians, In Press). Although the same regulatory base is being used, the system has been expanded to incorporate more intensive examinations of new biotechnology-based products. For instance, following the rulings that canola was acceptable as a food and feed, the regulatory system operated smoothly, with the single largest hurdle being the provision in the Seeds Act that required new varieties be better than a reference variety. There was little or no further review of the varieties for their health or safety risks. In the mid 1980s, two major changes took place. First, the Seeds Act was revised, allowing any new varieties that were equivalent with the reference variety to be registered; shortly thereafter rules were enacted to allow for "confined" releases to assist with breeding and regulatory compliance. By 1988, the federal government had reviewed and worked to co-ordinate the existing system of regulations and added the Novel Foods Guidelines to complete the system that would review biotechnology-based products. The test of the system was the herbicide tolerant canola varieties produced by Monsanto and AgrEvo. They successfully applied for approval for confined field trials and began the field work. By 1992 each of the companies had identified the cultivars they would seek regulatory approval to commercialise (discussions with companies). Over the 1989-94 period, the two companies conducted more 400 confined field trials each, first to select their commercial lines and then to provide the scientific evidence to satisfy the regulatory system (CFIA homepage). Over the 1992-95 period, the companies provided data and information to Health Canada to meet the Novel Foods Guidelines, to Agriculture Canada for animal feed approval and variety registration and to Environment Canada for environmental approval. In each case, the approvals were bunched into a short time period (all

approvals to proceed came within six months of the others for each variety, CFIA). Since then, the regulatory system has been streamlined, with the Canadian Food Inspection Agency assuming responsibility in 1997 for all the regulatory function except the Novel Foods Guidelines, which continues to be managed by Health Canada. The lead regulatory division of the CFIA is the Plants Products Division, which is advised by the Advisory Committee on Plant Biotechnology Regulation. The objective of the Advisory Committee is to assist the Plant Products Division in identifying and developing principles and protocols in the regulation of genetically modified plants.

In Canada, pressure to develop the 'Guidelines for the Assessment of Novel Foods' (Sept. 1994) not only came from developments of GM canola, but also from the imminent approval of GM varieties of corn, soybeans, tomatoes, cotton and squash in the US. Therefore, it was crucial for Canada to develop an acceptable level of regulatory oversight for the presence of novel plants in the Canadian food supply. Further, in late 1999, Health Canada announced amendments to the Canadian Food and Drugs Law, established to clarify the approval process for novel foods. The amendments involved seven years of consultations with all stakeholders (World Food Law Monthly No. 19, 1999). There were three main amendments. First, a detailed definition of novel foods was established:

a) *a substance, including a micro-organism, that does not have a history of safe use as a food;*
b) *a food that has been manufactured, prepared, preserved or packaged by a process that:*
    i) *has not been previously applied to that food,*
    ii) *causes the food to undergo a major change, and*
c) *a food that is derived from a plant, animal or microorganism that has been genetically modified such that:*
    i) *the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism*
    ii) *the plant, animal or microorganism no longer exhibits characteristics that were previously observed*
    iii) *one or more characteristics no longer fall within the anticipated range for that plant, animal or microorganism*

The definition also specified that there are three types of variations that place the foodstuff outside the anticipated range: variations in the composition, structure or nutritional quality outside the conventional range; variations in the manner in which the food is metabolised in the body; and variations in the microbiological safety, the chemical safety or the safe use of the food relative to conventional products. Second, it established mandatory pre-market notification for the commercialisation of novel foods. Health Canada had considered pre-market approval but found that this would add little to the safety while adding extensively to the cost. Pre-market notification requires 45 days prior notice to HC before sale or advertisement of any novel food. HC must give its response on the acceptability of the novel food within the 45 days. Additionally, HC can suspend the sale or advertisement if additional information is required. Third, the amendments also detailed procedures for assessing the safety of novel foods. A notable concept here is that of 'prior safe use as a food' which allows HC to approve the notification of a novel food that has been accepted by certain other countries. In this sense, this concept represents a form of regulatory mutual recognition.

There is a horizontal regulatory safety net in Canada, Environment Canada's Canadian Environmental Protection Act (CEPA). Novel products that do not fall under the regulatory oversight of either the CFIA or Health Canada are under the notification of new substances requirements of the CEPA. The federal regulatory system is identified in Table 6.3.

An important aspect of Canadian regulatory oversight for GM crops is that, unlike US regulations, there is scope for Canadian regulators to base decisions upon 'effectiveness' or social benefit. As will be shown (Chapter 7), this is similar to the European fourth hurdle of regulatory oversight (safety, quality, efficacy and effectiveness). As was previously discussed, US regulatory decisions tend to adopt the position of letting the market decide a product's social benefit, provided the product is safe or of sufficient quality and exhibits its claimed attributes.

The Canadian policy on labelling products made from GM crops is similar to that in the US. As the Canadian regulatory system is based on novelty, not the use of GM techniques, the labelling policy does not support process-based labelling for the consumer's right to know that GM techniques have been used. An added dimension to the Canadian labelling policy is that Canada is currently the chair of the Codex Committee on Food Labelling (see Chapters 3.2.1.C and 5.3.1.C).

Product	Act	Contacts
Agri-food products (meat, dairy, eggs, fruits, vegetables, honey, maple products)	• Meat Inspection Act • Canada Agricultural Products Act	CFIA, Science & Technology Services
Livestock feeds, additives (e.g. novel feeds)	• Feeds Act • Guidelines for the Assessment of Plants with Novel Traits as Livestock Feed (Proposal 94-04 22 Nov. 1994)	CFIA, Feeds Section, Plant Products Division
Fertilizers, supplements (e.g. biofertilizers)	• Fertilizers Act	CFIA, Fertilzier Section, Plant Products Division
Plants (including plants with novel traits and with genetically engineered micro-organisms)	• Seeds Act (field trials) • Plant Protection Act 1990 • Canadian Environmental Protection Act (1 Sept. 1997) • Procedures for the Registration of Crop Varieties (1 October 1994) • Field Testing Plants with Novel Traits (Directive 95-01 6 Jan 1995) • Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits (Directive 94-08 16 Dec 1994)	CFIA, Plant Biotech Office, Plant Products Division, and Environment Canada
Genetically Engineered (Novel) Foods	• Regulated in the same manner as that produced by conventional methods. • Approved for safety prior to reaching the food production system • Novel Food Guidelines of the Food and Drugs Act. • no labelling required	Health Canada, Food Directorate, Food Inspection Directorate
Source, http://www.cfia-acia.agr.ca/english/		

Table 6.3 Canadian Agricultural Biotechnology Regulations

Canadian efforts at international regulatory integration are led by the CFIA's Biotechnology Strategies and Coordination Office. This Office co-ordinates Canadian regulatory policies with those developed at international fora such as the WTO and the international negotiations for the Biosafety Protocol. This Office advises trade policy makers and trade negotiators in AAFC and the Department of Foreign Affairs and International Trade (DFAIT).

Similar to the US regulatory system, the Canadian system may be characterised according to the regulatory principles of the scientific and social rationality approaches (Table 6.4). The general interpretation of the Canadian approach is that it is largely congruent with the scientific rationality paradigm. There is, however, an important deviation regarding the debates over science v. other

legitimate factors in risk assessment and risk management. In the risk assessment procedure, the Canadian approach permits food products to be assessed according to all four regulatory hurdles. In the risk management procedure, the Canadian approach permits other legitimate factors such as socio-economic factors in risk management decisions rather than just a narrow focus on risk reduction and prevention.

With respect to the specific regulatory principles associated with GM crops, the regulatory approach employs the scientific interpretation of the precautionary principle. Second, the system is novel product based where substantial equivalence is assumed for all non-novel GM products. Third, regulatory authority is associated with vertical jurisdictions. Fourth, participation in the regulatory decision-making process is limited to specific, traditional actors. Finally, labelling policy does not support GM labelling for the consumers' right to know.

	Scientific Rationality	Social Rationality
General Regulatory Issues		
Tradition	✓ Regulatory Independence	
Belief	✓ Technological progress: Enhances growth and development leading to higher social regulations – a regulatory race to the top.	
Type of Risk	✓ Recognised ✓ Hypothetical	
Substantial Equivalence	✓ Yes	
Science or Other in Risk Assessment		✓ Risk assessments may be based on all four regulatory hurdles
Burden of Proof	✓ Traditional: Minimise Type I (Rejected when safe)	
Risk tolerance	✓ Minimum	
Science or Other in Risk Management		✓ Risk management may consider other legitimate factors beyond on risk prevention and reduction: Socially Responsive
Specific Regulatory Issues		
Precautionary Principle	✓ Scientific Interpretation	
Focus	✓ Product-based, Novelty	
Structure	✓ Vertical, Existing structures	
Participation	✓ Narrow, technical experts ✓ Judicial decision-making	
Labelling	✓ Safety or Hazard only Voluntary, market-based for the consumers' right to know	

Table 6.4 Canadian Regulatory Approach Checklist

The Canadian regulatory approach may be assessed from both an economic and a social perspective.

Economic Perspective

From an economic perspective, the Canadian system has operated relatively efficiently, approving by 1997 more than 3,800 field trials, 29 plants with novel traits for feed and 3 novel foods. It has been able to achieve this flow of regulatory decisions by assuming substantial equivalence and by limiting participation in the decision-making process to the proponent and the regulators. The commercial effectiveness of Canadian regulations to GM crops is favoured by the biotechnology industry. A 1994 survey revealed that 'improving the regulatory approval process' was considered the most important task for government by the biotechnology industry, and support for the industry has influenced regulatory development (Ernst and Young, 1995).

Social Perspective

Citizens, consumer and environmental organisations along with provincial governments, while allowed relatively free access to applications and specific decision documents through the CFIA website, are not allowed to have any say in the science based system. So far, in Canada, that has not created any backlash by either the major lobby groups or the general public.

From a social perspective, the Canadian system for food safety in general has been proactive in establishing an institutional framework designed to build consumer confidence. In 1997, all food inspection and assessment functions were transferred from Agriculture and Agri-Food Canada (AAFC) and to the new Canadian Food Inspection Agency (CFIA). Essentially, governmental promotion of the agriculture sector was separated from regulatory activities associated with agri-food and environmental protection issues. By all accounts, this institutional restructuring has further enhanced consumer confidence in the government's regulatory role. Specifically, regulatory oversight for agricultural biotechnology is shared between Health Canada, which assesses novel GM foods and the CFIA and Environment Canada which address specific consumer and environmental health and safety issues associated with GM agricultural products. However, similar to the US regulatory system, the Canadian system may have difficulty incorporating social dimensions into the regulatory process in the event that the use of GM materials in the both the food supply and environment becomes a highly politicised issue. Citizens, consumer and environmental groups as well as provincial departments and agencies, who have

relatively little access to the decision-making process, may demand both greater transparency and participation. The Canadian Biotechnology Advisory Committee (CBAC) has been established as the federal government's conduit for the two-way flow of information between regulators and the general public. As well, in late 1999 the Federal Government announced the creation of a Scientific Advisory Committee to examine what type of agricultural biotechnology products are coming, what are the anticipated short- and long-term health implications, what are the international developments in this area and, consequently, what type of scientific regulatory capacity is required in Canada in order to ensure the safety of agricultural biotechnology products. This scientific committee will advice Health Canada, the Canadian Food Inspection Agency and Environment Canada.

6.4 North American Regulatory Integration

Given the significant linkages between Canadian and US agriculture, and especially the respective research efforts, regulatory integration was necessary to provide consistent regulatory oversight for industry promotion and consumer and environmental protection.

The two lead regulatory agencies (APDHIS of the USDA and CFIA) have worked to streamline the approvals of products in the two countries. In the past the two agencies have undertaken simultaneous reviews of GM plants prior to their commercialisation and have shared data and observations informally. In 1998, USDA, CFIA and Health Canada regulatory officials met to compare and harmonise, where possible, risk assessment procedures such as the molecular genetic characterisations components of the regulatory review process for GM plants. That is, they examined opportunities to streamline the science-based and rules-based approach to risk assessment

The Canadian – US integration of agricultural biotechnology regulations is congruent with agricultural trade liberalisation commitments made under the original Canada-US Trade Agreement (CUSTA) and continued in the North American Free Trade Agreement (NAFTA). Both agreements are free trade agreements based on sovereignty and regulatory competition with no goal of deep integration. The objective, in general, is to engage in a long-term regulatory integration but within a traditional trade framework. For instance, under the CUSTA, the US and Canada established Technical Working Groups (TWG) to deal with specific sectoral trade

issues. The most important TWG for the issues dealing with GM crops is the TWG on seeds. Under the NAFTA the TWG were trilateralised and two permanent committees were established to ensure continual dialogue on issues of regulatory barriers to trade; the Committee on Standards Related Measures and the Committee on Sanitary and Phytosanitary Measures. Further, according to a 1995 NAFTA Memorandum of Cooperation (MoC) called for both the regular reporting of food standards to improve co-ordination efforts and to co-ordinate a 'NAFTA' position on food standards in international fora such as Codex and the WTO.

This level of regulatory integration between the two countries is made possible because the regulatory approaches have each adopted the scientific rationality approach to regulating GM crops. Further, the regulatory integration ensures that there are few insurmountable social regulatory barriers to trade.

There are, however, important limits to the type of regulatory integration pursued under the NAFTA. Most importantly, the regulatory integration remains subject to the traditional trade principles of regulatory sovereignty and host country control. That is, the regulatory integration would not likely work in the event that the one jurisdiction employed a scientific rationality approach while the other jurisdiction employed the social rationality approach.

6.5 Conclusions

The North American approach to regulating GM crops is summarised in Table 6.5. In general, it reflects a scientific rationality approach to technological progress driven initially by scientists many years before commercialisation issues were raised. It is supported and influenced by economic interests and, as a result, it is conducive to the North American commercialisation lead in agricultural biotechnologies.

While being commercially friendly, this approach does have some significant drawbacks in its social responsiveness. It is unlikely that that the North American approach can shift enough towards the social rationality paradigm to meet social interests without abandoning the scientific regulatory principles. In other words, should a crisis of confidence emerge in North America in the magnitude of that in the UK (Chapter 7.3.1) the North American approach may have to make some rapid amendments in favour of social rationality principles.

Regulatory integration dealing with social regulatory barriers is made easier when two jurisdictions have adopted the same regulatory principles as with Canada

and the US. The difficulty is, of course, integrating regulatory approaches that have adopted divergent paradigms.

	North American Regulatory Approach
Tradition	Regulatory Independence
Paradigm	Scientific rationality
Precautionary Principle	Scientific Interpretation
Focus	Product or Application-based, Novelty
Structure	Vertical, existing regulatory agencies
Decision-Making	- Narrow participation - Judicious
Labelling	Voluntary, market-based
Integration	Economic Integration according to Regulatory Competition

Table 6.5: Characterisation of North American Regulatory Approach

CHAPTER SEVEN EUROPEAN REGULATORY APPROACH

7.1 Introduction

Similar to the North American regulatory approach the European approach must strike a delicate balance between technological progress in order to remain competitive in the frontier technology and technological precaution in order to assuage politically powerful concerns about consumer and environmental protection. The objective of this chapter is to examine both the promotion and regulation of GM crops at the EU level and within the United Kingdom.

Prior to this, it is crucial to identify the European perception of the agriculture sector as this provides important context or background to European efforts to both promote and regulate GM crops. As previously mentioned, in North America agriculture is perceived to be an industry. This is very different from the general perception of the agricultural sector in Europe which is generally perceived (especially Western Europe) is perceived to be more than just an industry. It fulfils a 'multi-functional' role including supporting the rural way of life, preserving the culture and heritage of the countryside, ensuring the welfare of animals (both livestock and wildlife) and protecting the environment. According to this EU model of agriculture, farming is a special kind of endeavour forming the last line of defence between the country and urbanisation. In addition, European consumers have faced several severe food safety crises that have undermined the public trust in regulators and scientists (NCC, 1998; Consumers' Association, 1997; Grove-White *et al.*, 1997; Sheppard, 1997). The implication of this for credence goods such as GM crops is that there is little trust among consumers in the traditional sources of risk information. Combining the multi-functionality role with the lack of public trust results in a European agricultural sector under considerable scrutiny as a well-politicised issue.

7.2 Agricultural Biotechnology in the EU

The EU has considerable capacity in agricultural biotechnologies. For instance, European firms on the frontier of GM crop development include Agrevo (Germany), Astra-Zeneca (UK), Hoechst (Germany), Novartis (Switzerland) and Rhone-Poulenc (France). This capacity must reconcile both strong national competitiveness drivers in Member States with the EU model of agriculture and the

significant public concern about the use of GM crops in the food supply and in the environment.

An additional dimension to the European promotion and regulation of GM crops is the relationship between the EU-level and the approaches and initiatives of the various member states. The competing forces of regulatory centralisation and subsidiarity exist not only between the EU level and trading partners, but within the EU between European services and Member States.

7.2.1 EU Promotion of Agricultural Biotechnology

Developing a competitive posture in biotechnology has been a strategic priority in Europe for nearly two decades. Originally, DG XII (Science, Research and Development) led the push, although there have been several initiatives including (from Haerlin, 1990; Sorj *et al.*, 1989; Theodorakopoulou and Kalaitzandonakes, 1999):

1. Biotechnology Framework Programme (BFP), 1983 – promotion and marketing
2. Biotechnology Engineering Programme (BEP), 1982-86 – ECU15 million
3. Biotechnology Action Programme (BAP), 1986-89 – ECU56 million
4. Biotechnology Research and Innovation for Development and Growth (BRIDGE)
5. Euro Collaborative Linkage of Agriculture and Industry through Research (ÉCLAIR) – ECU 80 million to develop new plants for industrial uses
6. Food-Linked Agro-Industrial Research (FLAIR) – ECU25 million for transnational food safety, quality and competitiveness projects, creating value for agricultural biotechnology products
7. European Commission's Innovation Program: a supply-driven initiative to support the commercialisation of advanced technologies.

In 1983, DG XII of the European Commission examined the competitive position of European biotechnology relative to the respective positions in the US and Japan. The Commission's report, entitled *Biotechnology in the Community* (Europeam Community, 1983) sought to develop a comprehensive biotechnology strategy for the EEC that would improve its global competitiveness.

In 1991, the Commission's Biotechnology Co-ordinating Committee presented a paper to the Council and the Parliament entitled *Promoting a Competitive*

Environment for Industrial Activities Based on Biotechnology Within the Community outlining regulatory reform required to improve competitiveness.

In 1994, the importance of biotechnology in the EU was again highlighted by the White Paper on Growth, Competitiveness and Employment stating that "the growth rate of industries based on modern biotechnologies is expected to be substantial." (European Commission, 1994). Specifically, capacity in agricultural biotechnology is an important competitveness issue because restructuring of the CAP would involve the retreat of domestic farm support and agricultural biotechnology can potentially fill the gaps. Further, other nations, especially in North America, continue to invest both publicly and privately in the research, development and commercialisation of new agricultural biotechnology products. In fact, recent research has concluded that continued restrictive regulatory policies in the EU will produce a global allocation of biotechnology capacity where North America will be the dominant region for the R&D into biotechnology and Southern countries will become the producers of resultant GM crops while Europe will become the dominant producer of labour-intensive sunset technologies (Weatherspoon, *et al.*, 1999). Such a result seems unacceptable from the point of view of the 1994 White Paper.

Joly and Lemarie (1998) have argued that Europe is already at a competitive disadvantage in GM crop technologies targeted at production-improved varieties and due to cumulative innovation effects it is unlikely to catch up (Joly and Lemarie, 1998). From a competitiveness position, the solution is more direct promotion of GM crop development focused on output-improved varieties, Bio-Engineered products and genomics. Indeed, a recent industrial initiative in France has the mandate of closing the technology gap. The GenoPlante Initiative is targeting the development of GM varieties of rice, corn, wheat and colza, which are important crops in French agricultural production. Through this initiative public research (INRA, CIRAD, ORSTOM, CNRS) is co-ordinated with private research efforts (LimaGrain/ BioGemma and Rhone-Poulence). If successful, it can be expected that this type of initiative will also be adopted at the EU level (Joly and Lemarie, 1998).

Along with France, other member states also have biotechnology promotion initiatives (Financial Times, 20 April 1999). For instance, in 1995 the UK launched the 'Biotech Means Business' initiative followed up in 1998 by the £13 million pound BioWise program designed to encourage industry to use biotechnologies. It has been estimated that up to 1998, the UK has spent £176 million through the Biotechnology

and Biological Sciences Research Council (Sheppard, 1997). The dominant biotechnology program in Germany has been BioRegio an initiative that provides matching Federal-Lander funds for start-up biotechnology companies. However, in late 1999 Germany announced a new initiative, the 'BioProfile Programme' which aims to spend DM100 million on the promotion of Germany biotechnology to establish Germany as the European leader in the field (AgraFood Biotech No. 18, 1999).

There are also several organisations actively promoting agricultural biotechnology in the EU. This includes: EuropaBio; European Science Foundation (ESF); European Molecular Biology Organisation (EMBO); and the European Federation of Biotechnology (EFB).

The EU promotion of GM crop development has, however, come under pressure from critics. Mindful of the implications of a loss in consumer confidence, the European Commission has recently suggested that it may cut the overt support to GM crop development because of consumer concern. Spending will continue in support of basic biotechnology techniques and procedures.

The EU is certainly behind North America in the commercialisation of GM crops. Yet, significant research efforts, both public and private are underway to close this gap.

7.2.2 The EU Regulatory System

It has been argued that the European regulatory approach reflects an accountability tradition of government regulatory intervention dominated by concerns over the democratic accountability of the discretionary decision-making power of regulators (Majone, 1994). In achieving accountability, regulatory decision-making resides with elected public officials. As a result, regulatory development and administration is very much subject to the day-to-day public interests dominating the concerns of elected officials.

Both food safety and environmental protection regulations in the EU have always pursued a dual objective: to ensure the free movement of products in the internal market while protecting consumers and the environment. Yet, there are important differences between food safety and environmental protection regulations. The legal basis of EU food safety regulations is derived from Article 100a of the Treaty Establishing the European Communities in which facilitation of the internal

market is the primary objective. On the other hand, the legal basis of environmental protection regulations tends to be Article 130r Title XVI Environment of the Treaty Establishing the European Communities in which protection of the environment is paramount, not facilitating the internal market. Hence, while food safety regulations are compelled to be market sensitive, environmental protection regulations are not. It will be argued that this difference in the legal basis encourages a shift in European GM crop regulations from food safety justifications to environmental protection justifications subject to less common market requirements.

It is important to place the development of both food safety and environmental protection regulations in the context of the 1985 White Paper on the Internal Market. This paper proposed to remove the politics from regulatory convergence among member states. In this sense, the food safety and environmental protection regulations for GM crops, based on consumer fears and subsequent political actions conflicts with the EU new approach to regulatory integration seeking to eliminate the politics from European regulatory development.

Policy development may be characterised according to a three-step procedure. The Commission initiates, the community debates and the Council, and increasingly the Parliament, decides (Phillips, 1991). Article 155 of the Treaty of Rome authorises the Commission to "formulate recommendations or deliver opinions on matters dealt with in this treaty, if it expressly so provides or if the Commission considers it necessary". According to Article 149 the Commission then takes an active role in formulating policy development at all three stages. Under Article 145, however, it is the Council which has final decision-making power, generally based on council consensus although voting procedures may apply. Hence, the Council can override the Commission and enact any regulatory approach it likes.

There are competing views on the nature of regulatory decision-making in the EU. On one hand, it is argued that the decision-making is narrow and technocratic and focused only on facilitating the internal market, with little scope for broader participation. On the other hand, it is argued that this is an oversimplification of European governance and that the case of biotechnology policy making demonstrates the significant political influence of social concerns in regulatory development (Landfried, 1997).

Given this regulatory context, the objective now is to identify the development of GM crop regulations in the EU. It is important to note that there were, and continue

to be, divergent views between Member States and the EU services and also divergent views within the various services of the EU on the opportunities and risks of agricultural biotechnology. These divergent views have been crucial in the regulatory development process. With respect to divergent views of Member States, there have been several cases where Members have imposed unilateral moratoriums on the field trial plantings of GM crops. While these instances will be examined in greater detail below it is important to note that membership in the EU has meant that members lose the sovereign right to impose unilateral regulatory actions, and the legality of these moratoriums is in doubt.

The first European policy proposal dealing with biotechnology regulations was developed by DG XII in 1978. This proposal was for a binding Council Directive that would require all biotechnology research and other work to notify and seek authorisation from the competent national authority, who in turn would advise DG XII on approvals in order to build up a base of biotechnological knowledge about risks, problems and experiences. This proposed directive was notable for three reasons. First, it employed the scientific interpretation of the precautionary principle which was also recommended in the 1976 US NIH guidelines. That is, controlled laboratory research was permitted even though the risks were uncertain because such research would produce risk information leading to a better understanding of the risks.

Second, the proposed directive was horizontal in nature, applying to the process and production methods of all biotechnology research regardless of the proposed or intended end-use. The reason for horizontal guidelines was to create an essential minimum requirement for research activities across all Member States. Yet, this proposal was in conflict with the NIH guidelines that suggested there were no significant risks associated with the use of biotechnology, rather the risk was linked to the proposed end-use. The NIH recommended product-based regulations while the proposed directive was for technology-based regulations.

Third, the proposed directive allowed competent authorities in each Member State to approve or reject research initiatives, rather than centralising decision-making at the EEC level.

In 1980, the directive proposal was replaced by a proposal for a non-binding recommendation adopted by the Council in June 1982 as the *Council Recommendation Concerning the Registration of Work Involving Recombinant Deoxyribonucleic Acid.* The proposed directive was softened to a non-binding

recommendation in reaction to the relaxation of guidelines by the NIH. Essentially, the scientists active in the nascent research on biotechnology projects realised that previous, precautious assumptions about the risks from genetic modification were exaggerated, and guidelines and recommendations were relaxed.

From a regulatory perspective, DG XII's 1983 report *Biotechnology in the Community*, was notable for two reasons. First, the report did not explicitly call for a horizontal regulatory policy for biotechnology, which was part of the 1982 Council Recommendation. Instead, it supported the product-based regulatory approach which appeared favourable to competitiveness in the US. Second, anticipating the public response to modern biotechnology, it sought "to ensure regulatory provisions to maintain national standards of public safety; and to this end, to monitor the social dimensions of biotechnology" (European Commission, 1983). Including the vague reference to the social dimensions of biotechnology is essentially how many actors gained direct participation in the regulatory process. That is, the scientific and technocratic participants were joined in the decision-making process by social interests such as consumer and environmental organisations who claimed to represent the social dimensions of biotechnology.

In 1986, the Commission submitted a Communication to the Council entitled *A Community Framework for the Regulation of Biotechnology* (European Commission, 1986). This communication was the EC response to the OECD recommendation on how to deal with biotechnology regulation. It called for a "clear, rational and evolving basis for biotechnology regulation" and for regulatory harmonisation of the EC regulations with other countries. Indeed, it may be argued that North American and European regulatory approaches to biotechnology shared regulatory principles and were, at this point, on a similar trajectory. The focus on product-based regulations, the scientific interpretation of the precautionary principle and the jurisdiction of existing regulatory frameworks were supported by the OECD and other international organisations. At this point, international harmonisation appeared to be a real possibility. This was not to last. Internal European conflicts significantly challenged the regulatory principles. These conflicts existed between Member States, between the European Parliament and the Commission and between directorates within the Commission.

In 1987 the European Parliament's Viehoff Report made recommendations on appropriate regulations for environmental release of genetically modified organisms

(European Parliament, 1997). This report was an initiative of the European Parliament's Committee on Energy, Research and Technology, and the rapporteur was Phili Viehoff. Six Parliamentary Committees were involved: Environment and Consumer Protection; Economic Affairs and Industrial Policy; Agriculture and Food; Energy, Research and Technology; Social Affairs and Employment; Legal Affairs and Citizens' Rights. The report recommended that the "Commission give priority to studying the problems posed by the potential release into the environment of genetically engineered natural micro-organisms" and demanded a moratorium on such releases "until binding Community safety directives have been drawn up". The report also called for the harmonisation of Member States' procedures for risk assessment in order to establish common environmental protection measures.

The Viehoff Report was notable for several reasons. First, the range of parliamentary committees involved, indicative of the broad range of consumer concerns, established a precedent for what was meant by the social dimension of biotechnology. Second, the report's recommendations explicitly suggested that technology-based, binding Community directives were necessary, rather than a patchwork of national regulatory approaches. Community regulatory harmonisation and centralised decision-making was viewed as the only appropriate way to deal with the transnational uncertainties and risks associated with the environmental release of genetically modified materials. In fact, this was a direct attempt to prevent unilateral member state action, in favour of a co-ordinated Community regulatory approach. Third, the report focused directives on Community environmental safety and health, rather than on facilitating the Single Market. This was a crucial development, as will be shown, because the report provided a foundation for DG XI (Environment) to argue that regulatory precaution must be according to the social interpretation of the precautionary principle and that the legal basis of horizontal biotechnology directives must be Community protection under Article 130r of the Treaty Establishing the European Communities. The report called for a moratorium on research until binding, harmonised and horizontal directives were in place. Therefore, the Viehoff Report departed significantly from the scientific rationality regulatory trajectory of product-based regulations employing the scientific interpretation of the precautionary principle. Indeed, this report represented first move towards the social rationality trajectory.

With respect to the inter-Commission conflict, it has been argued that it was due both to genuine differences in regulatory ideology and philosophy and to territorial disputes between vertical regulatory jurisdictions (Patterson, 2000). In terms of ideological and philosophical differences DG III (Industry), DG VI (Agriculture) and DG XII (Science, Research and Technology) all supported the scientific rationality regulatory principles adopted in the NIH guidelines, and supported by Canada and the US. Further, with respect to regulatory integration, these directorates tend to reflect the economic integration approach. For instance, a November 1999 European Commission Report by DG II (Treasuries and Financial Affairs) claimed that agricultural liberalisation, not protectionism, is the way for developed countries to experience substantial welfare gains and improvements in environmentally sound and sustainable agriculture (European Commission, 1999). The client base of these directorates was mostly industry and hence, commercial objectives remained influential. This is not to suggest, however, that these directorates were not interested in protecting human and environmental health and safety. They simply perceived that the potential risks or hazards were from products, not from technology.

On the other hand, the ideology and philosophy of DG XI (Environment), with support from DG XXIV (Consumer), favoured a social rationality approach to regulating risks, employing new horizontal directives that cut across the various mandates and jurisdictions of vertical directorates. Further, wide actor participation was supported in regulatory decision-making in order to preserve the focus on the social dimensions of biotechnology. The social interpretation of the precautionary principle was to be employed to ensure the highest level of consumer and environmental protection in the face of speculative risk or uncertainty. This regulatory philosophy was congruent with the Viehoff Report and, hence, enjoyed significant support from the European Parliament. Since the client base of the two directorates included consumer and environmental NGOs, an important objective of the regulatory focus was on assuaging public concern and fear by creating the impression that biotechnology was well controlled in both the food supply and in the environment (Patterson, 2000). In essence, the regulatory focus was on consumer perceptions of risk rather than hypothetical risk demonstrated through scientific risk assessment procedures.

In terms of the territorial disputes across vertical regulatory jurisdictions, it has been argued "no DG wanted to cede autonomy and regulatory authority to another DG

in an area which they believed fell squarely into their policy domain" (Patterson, 2000). Yet since biotechnology is a process facilitating product development across a wide spectrum of product categories, jurisdictional overlap was inevitable.

There were several inter-Commission initiatives established to deal with jurisdictional overlap and to facilitate improved regulatory co-ordination within the Commission. As a response to the 1983 Commission report on European competitiveness in biotechnology, the Biotechnology Steering Committee (BSC) was established in 1984 (Cantley, 1995). There were four directorates which initially participated; DG III, DG VI, DG XII and DG XIII (Information, Market and Innovation), however, participation was open to all DGs where concerned. Administratively, DG XII chaired the BSC while the directorate's Concertation Unit for Biotechnology in Europe (CUBE) was the secretariat. DG XI became involved in the BSC when potential environmental risks were identified and discussed. Characteristic of all discussions about biotechnology, the topics covered by the BSC were of a very technical, scientific nature. In order to effectively deal with the technical nature across the various regulatory jurisdictions the BSC formed the Biotechnology Regulations InterService Committee (BRIC) (Cantley, 1995).

Despite the differences between the European Parliament and the Commission and the differences within the Commission, the need to develop integrated, Community-wide measures clarifying the use of biotechnology remained. In fact, three horizontal directives were being developed in the late 1980s. The first two legislative efforts were focused on establishing measures for the contained use of genetically modified micro-organisms to ensure protection of human health and the environment. These legislative efforts resulted in Council Directive 90/219/EEC of 23 April on the contained use of genetically modified micro-organisms (European Commission, 1990a) and Council Directive 90/679/EEC on the protection of workers from the risks of exposure to biological agents (revised by Council Directive 93/88/EEC). The third legislative effort resulted in Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (European Commission, 1990b). The focus of the following discussion will be on Directives 90/219 and 90/220.

With respect to Directive 90/219 both DG III and DG XI were responsible for developing the legislation, that is they were co-chef de file. The importance of chef de file lies in the fact that the DG, in developing the legislation, is responsible for setting

the policy parameters, such as the legal basis for the legislation. Further, the chef de file then presents the draft directive to the corresponding Committee at the Council of Ministers. Recall that there were significant philosophical differences between the directorates regarding the regulation of biotechnology. Reconciling these differences required compromise. For example, DG III and DG VI were both initially successful in exempting specific product categories traditionally under their jurisdiction from the draft directive. That is, 90/219 would only apply to those products not covered under existing product legislation. However, the efficacy of the compromises was limited by the fact that DG III had much less resources to devote towards the legislative development than did DG XI (Cantley, 1995). There are two results of this. First, DG XI changed the legal basis of the directive from Article 100a of the Treaty Establishing the European Community, to Article 130r. Second, DG XI dropped the compromise with DG III and DG VI to exclude traditional product categories. These unilateral amendments prevailed because the draft directive was then put before the Council of Minister's Committee of Environmental Ministers. Therefore, despite the fact that the directive is supposed to represent the entire Commission, in reality directives can be dominated by particular directorates and their philosophies, which is then supported by the corresponding committee at the Council (Patterson, In Press). Indeed, it has been argued that even the inter-service BRIC had little influence upon the final directive because neither it, nor the BSC were decision-making bodies, they were only consultative groups which could be, and were ignored (Cantley, 1995).

The final Directive 90/219 was focused on protecting Community health and the environment from the contained use of genetically modified micro-organisms. Similar to the 1976 NIH guidelines, 90/219 divided risks into two groups. Also, new facilities must notify competent national authorities of their intention to conduct genetic modification research so that the authorities can ensure that appropriate protection measures are in place and that DG XI is notified. The directive also permitted Member States to consult as widely as deemed appropriate to incorporate the social dimension in research approvals. Finally, the directive contained provisions about mandatory responses to emergency situations[1].

The Directive 90/220 on the deliberate release into the environment of genetically modified organisms was intended to provide a comprehensive horizontal

[1] For a legislative summary see: www.europa.eu.int/scadplus/leg/en/lvb/121157.htm

regulatory oversight ensuring uniform internal market conditions while promoting human and environmental health in all Member States. The scope of the directive was plants, animals and micro-organisms where environmental release for either field testing or commercial applications required an environmental risk assessment. It shared many developmental aspects with 90/219, except for one major difference; DG XI was sole chef de file for this legislation. The legal basis of 90/220 was also changed from Article 100a of the Treaty Establishing the European Community to Article 130r (Patterson, 2000) and there were no product exemptions from the final legislation despite some early compromises. The importance of this development lies with the fact that this directive also established the measures relevant to placing products made from GM crops in the European marketplace. Similar to 90/219, both DG III and DG VI sought product exclusions from the draft directive. The original compromise excluded product categories such as medical products, veterinary products, animal feeds and foodstuffs from the horizontal legislation because they were subject to risk assessments according to specific European product legislation (European Commission, 1988). However, this compromise was dropped and the relevant clause was changed in the Directive to read:

> *Consent may only be given for the placing on the market of products containing or consisting of GMOs provided that...the products comply with the relevant Community product legislation and the products comply with this part of the directive, concerning the environmental risk assessment (European Commission, 1990b).*

Therefore, GM products faced regulations from both vertical product legislation and from the horizontal regulations under 90/220 before they could be placed on the market (Patterson, In Press). Similar to Directive 90/219, Directive 90/220 was also presented to the Council's Committee of Environment Ministers. The Directive outlines that:

> *Any person wishing to undertake a deliberate release of a genetically modified organism (GMO) must submit a notification to the competent authority of the Member State within whose territory the release is to take place. This notification shall include a technical dossier of information including a full risk assessment, appropriate safety and emergency response measures*

and, in the case of products, precise instructions and conditions for use[2].

Further, according to both the Directives, once a product is approved under either 90/219 or 90/220 a GM product cannot be restricted, prohibited or impeded by individual Member States for deliberate environmental release or market placement.

The original Directive 90/220 had two important exemptions. First, it did not include products derived from GMOs, only live GMOs. It was intended that vertical or sectoral legislation would be developed to deal with products derived from GMOs. Second, the directive did not initially mention labelling requirements for the consumer's right to know. The regulatory requirements for labelling and packaging were amendments to the directive.

It is important to note that neither 90/219 nor 90/220 considered any risk category as being so great as to require a moratorium. It has been argued that this meant that despite the strong environmental influence the directives did not accept speculative risk as a basis for regulations and, hence, did not go as far as many environmental NGOs would have liked (Wheale and McNally, 1990). In this sense, although the original directives supported precaution in the application of biotechnologies, they did not support an outright ban. With respect to precaution, Article 16 of 90/220 allows Member States to unilaterally impose a provisional ban given "justifiable reasons to consider that a product which has been properly notified and has received written consent under this directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product in its territory". An amendment to Directive 90/220 which proposed a five-year partial moratorium on environmental release was defeated by a margin of only one vote in the European Parliament in June 1989 (Schmid, 1989; Dickman, 1989). Also, the report by the European Parliament's Committee on the Environment called for strict legal liability applying to firms conducting deliberate releases. This would mean that any individual or organisation claiming for damages due to environmental release would not have to prove that the responsible agent acted negligently. Instead, the claimant simply has to show that the damages were caused by the actions of the releasing agent (European Parliament, 1989). The logic behind this, is that those releasing GMOs, knowing that they are subject to strict liability laws, would be more

[2] Legislative summary: www.europa.eu.int/scadplus/leg/en/lvb/121158.htm

diligent in ensuring that the release is safe. This type of liability is similar to US liability. In fact, this amendment was supported by a 1989 report of the UK Royal Commission on Environmental Pollution which went further by recommending also that released GMOs should contain a unique and publicly registered genetic marker so that the source of organisms in the environment can be readily identified (Royal Commission on Environmental Pollution, 1989). Therefore, at this point, the EU regulatory approach still reflects aspects of the scientific rationality paradigm.

Another crucial criticism of both directives is that neither included provisions for the public dissemination of information nor provisions for public inclusion in the decision-making process (Haerlin, 1990). Therefore, despite the explicit broadening of the remit of the directives to include the social dimensions of biotechnology and the provisions for Member State consultation on approvals, there was still significant dissatisfaction with the degree of public input in the approval process.

With respect to 90/220, the entry point for seeking EU approval is through a competent national authority of a Member State, known as the rapporteur, chosen by the company making the submission. The competent authority must review the application including the technical dossier with the full risk assessment within thirty days and provide a direct recommendation to the Commission for approval or rejection along with an application summary. The Commission then circulates the rapporteur's recommendation along with the application summary to Member States for a sixty-day comment period. Member States may hold public consultations to discuss the application. In the event of approval by all Member States, the rapporteur grants deliberate release or product placement consent to the applicant. In the event of rapporteur approval but a rejection by another Member State, the Commission takes the final decision according to an Article 21 Committee of qualified majority voting. Consent is binding on all Member States.

The two Council Directives, 90/219 and 90/220 were met with significant criticism from scientists, industry and from trading partners, especially the United States. Scientific communities claimed that after nearly two decades of research, there was no evidence that rDNA techniques were associated with an increased level of risk and hence, there was no justification for technology-based regulations. Moreover, they claimed that both directives were based on non-scientific criteria and were unduly burdensome to the research process (Cantley, 1995). Essentially, the scientific community argued that scientific rationality should prevail over social rationality.

Industry participants were also very critical of the horizontal, technology-based directives. In June 1989, several pioneering biotechnology firms in Europe formed the Senior Advisory Group on Biotechnology (SAGB) in order to lobby at the European level for legislation conducive to biotechnology research and development (Patterson, In Press). Although the SAGB was unsuccessful in altering the directives, it was notable for its horizontal lobby efforts. This group was especially concerned with the scope of regulatory consultation beyond a science-basis.

Other countries, especially the United States, were concerned about the significant departure of the EU regulatory approach from the regulatory principles supported by the US, along with Canada and the OECD. Both directives represented a deviation from the initial similar regulatory trajectory developed in North America and within several international organisations (Chapter 5.2.6). The worry was that divergent approaches would yield divergent regulatory outcomes whereby products approved for deliberate release and commercial use in one jurisdiction, would not be approved in another jurisdiction. Indeed, this worry has become reality for GM crops approved as safe in North America.

In response to the negative reaction in 1990, the Commission established another inter-service body to consider the criticisms and to reform and co-ordinate the EU biotechnology policies. The Biotechnology Co-ordinating Committee (BCC) identified that the directives lacked focus on commercial issues relating to the functioning of the internal market. Essentially, the competitiveness issues associated with biotechnology were identified. This was outlined, for example, in two papers. First, was a communication from the Commission to both the Parliament and the Council entitled *Promoting a Competitive Environment for Industrial Activities Based on Biotechnology within the Community* (European Commission, 1991), largely drafted by the BCC. There were three main goals:

1. to ensure a coherent regulatory approach and an efficient and simplified interaction between sectoral and horizontal legislation (to eliminate the dual regulations)
2. to ensure existing legislation is kept under review to reflect rapid developments and technical and scientific progress
3. to streamline testing and authorisation procedures required for biotech products

The second paper was the 1994 White Paper on Growth, Competitiveness, and Employment (European Commission, 1994) which included biotechnology as a key sector. This paper called for

1. constant review of the dynamic developments
2. regulatory harmonisation with established international practice
3. greater public investment

Yet, critics argued that these two papers placed too much emphasis upon competitiveness, and too little emphasis upon the 'social dimensions' of biotechnology. For instance, it has been argued that governments within the EC are too focused on international competitiveness and are devising their science and technology policies to meet this goal. As a result, the public sector is claimed to be too involved with the private sector in promoting biotechnology and the traditional public protection roles are forgotten (Haerlin, 1990).

The pressures for regulatory approaches that facilitate international competitiveness remained very strong. Hence, given the negative reaction from scientists, industry and trading partners and given the apparent adverse impacts upon European competitiveness, reform of Directive 90/219 became a priority of the Commission and the remit of the BCC. Inter-service consultations were held as well as consultations with industry, environmental groups, scientific organisations and trade unions. The first amendment to 90/219 was drafted by the BCC and became Council Directive 94/51/EC (European Commission, 1994). This amendment was very contentious. The amendment was designed to facilitate greater European competitiveness in biotechnology. The Commissioner for the Environment, Ritt Bjergaard was displeased with the focus on competitiveness and the internal market. She drafted her own proposed amendments, which were much more sympathetic to consumer concerns about safety and environmental protection, regardless of the risk basis for these concerns. In fact, this proposal very much reflected a social rationality approach to regulating technology. This proposed amendment was presented to the College of Commissioners. This led to a counter proposal by DG-III and DG-XII, which was passed by vote in December 1995.

The second amendment to 90/219 was Council Directive 98/81/EC of 26 October 1998 (European Commission, 1998). The objective of this amendment was to reconcile 90/219 with the scientific knowledge and expertise of the risks that had been

acquired since the directive first came into force. There were three main amendments[3]. First, the administrative procedures for applying for and receiving approval for contained research were simplified. Second, the requirements for notification were linked to the graduated scale of risk, essentially making low risk research much easier. Third, based on the significant accumulated knowledge about GMOs, a list of GM micro-organisms that pose no risk to human health or the environment was included in the legislation.

In June 1994, the Commission announced its intention to review 90/220 however, this intention did not enjoy the same urgency as 90/219 for two reasons. First, DG-XI was sole *chef de file* of this directive and did not share a passion for 'competitiveness-based' regulations. Second, at this time, there was little European experience with deliberate environmental release of GM crops since their development was not as advanced as in North America.

The timeliness of the policy issue seemed to be farther off. The first amendment to 90/220 was Commission Directive 94/15/EC of 15 April 1994 (European Commission, 1994). Similar to the amendments of directive 90/219, the first amendment was motivated by desires to increase the focus of the directive on European competitiveness in biotechnology and on enhancing the internal market.

An important issue for the market placement aspects of 90/220 is labelling issues. The labelling of products derived from GMOs was, and remains an important social issue in Europe. The initial position of the EU on the labelling of the approved varieties of GM soya was that mandatory "labelling is only necessary when the final product has been substantially modified, which is not the case with 'Round –up-Ready' soya" (World Food Chemistry News, 1996). Further, according to the labelling policy the consumers' right to know was not considered an appropriate justification for a mandatory labelling scheme covering GM soya that was approved as safe because it was deemed substantially equivalent to non-GM soya. There was considerable dissatisfaction among consumer organisations, retailers and industry regarding the lack of concern for the consumers' right to know whether GMOs had been used in the product. These groups demanded a mandatory labelling policy for the consumers' right to know about the use of biotechnology in final goods, regardless of the safety or substantial equivalence of the GM product.

[3] For a legislative summary: www.europa.eu.int/scadplus/leg/en/lvb/121157.html

The regulatory reaction to these demands was the Novel Foods Regulation (EC) No. 258/97 (European Parliament, 1997). This regulation took four years to develop and was the first community-wide labelling legislation primarily focused on the consumer's right to know. The intent of the Novel Foods Regulation was to broaden EU regulatory oversight to include products derived from novel GM material, not just products containing viable novel GM material. This was a product-based regulation where the assessment of safety remained the jurisdiction of 90/220, the Novel Foods regulation was only for mandatory labelling requirements. This regulation was intended to fast-track regulatory approvals by increasing the transparency, certainty and stability of European regulations for Novel Foods. Further, there was considerable support for the Novel Food Regulations in both the European Council and the Parliament (World Food Chemistry, 1996).

As the name indicates, the Novel Foods Regulation was intended to deal with novel foods and food ingredients "whose nutritional value, metabolism or level of undesirable substances had been significantly changed by the production process". Such products were required to be labelled where the label must include: reference to how the product had been changed to make it novel; the presence of ingredients that might affect health (e.g. allergens); the presence of ingredients that might give rise to ethical concerns; and the presence of a genetically modified organism to meet the consumers' right to know. The attempt was to develop scientifically based mandatory labelling requirements consistent with international obligations and designed to convey neutral and transparent information about novel products. Specifically, with respect to the presence of novel GM material, mandatory labelling was required where the presence of modified protein was certain or where its absence could not be certified (as in the case of non-segregation). The Novel Foods Regulations encouraged the voluntary labelling of products that certainly do not contain novel GM material. And, similar to 90/220 Article 16, the regulations allow Member States to impose a unilateral ban "if new information or a reassessment of existing information suggests a risk or hazard to either human health or the environment".

However, there are two important aspects of the original Novel Foods regulations. First, the regulation is not applicable to food additives, flavourings or extraction solvents, which all may be GM material, because other community legislation dealt with these issues. Second, as discussed in Chapter 2.1.1 GM crops can be novel plants or alternatively they could be non-novel and substantially

equivalent to non-GM crops. As a result, the Novel foods directive did not explicitly address the consumer's right to know about the use of GM crops in foodstuffs, only the use of novel GM crops.

The second amendment to 90/220 represents DG XI's reaction to the Novel Foods Directive. The second amendment was Commission Directive 97/35/EC of 19 June 1997 (European Commission, 1997) enacted under DG XI's emergency allowance to amend community legislation. Annex III of the directive sets labelling and information notification requirements for all products made from GM material, whether novel or not. This Annex was essentially designed to override the vertical product legislation on Novel Foods developed by DG III, with the horizontal regulations of 90/220. DG XI aimed to fill the gaps by requiring mandatory technology or process-based labelling of all GM products approved for market placement in the EU, not just for novel products, by calling for mandatory labelling of GM products approved after 18 June 1997. DG XI wanted specific labelling rules for foods produced from GM crops, not just general labelling rules for all novel foods because novel foods are not necessarily foods produced from GM crops. Further, under Directive 97/35/EC firms were encouraged to voluntarily adopt the labelling requirements laid out in this directive for products made from the GM soya or maize crops approved prior to the 18 June 1997. Essentially, Annex III of 90/220 shifted the mandatory labelling policy from a novel, product-based focus to a technology-based focus. Then in September 1997, Council Regulation 1813/97 was adopted, effective 1 November 1997, which required mandatory labelling for the GM soya and maize. Thus DG XI used this amendment to dominate European product legislation with the horizontal biotechnology regulations.

The third amendment to Directive 90/220 was IP/97/1044 of the 26 November 1997. This was another labelling amendment which was focused on establishing the precise requirements referred to in the emergency Directive 97/35/EC. It included specific and mandatory label content rules.

Together, the Directives 90/219, 90/220 and the Novel Foods regulations are the three principle legislative texts dealing with GM crops in the European Union. However, there are other important regulations to identify, such as the general EU labelling laws as well as vertical, product legislation relevant to GM crops.

Council Regulation 1139/98: The Soya/Maize Regulation

The broad context of European foodstuff labelling law is outlined by the Council Directive 79/112/EEC (European Commission, 1979). This directive is intended to harmonise the legislation on the mandatory labelling of foodstuffs so as to ensure that products can move freely in the internal market and that consumers are informed and protected. The directive outlines that the label must contain, among other information, a list of the product ingredients; a requirement that is relevant for GM foods. In fact, follow-up work on the directive has been driven by continued concern with the use of GM soya and maize not considered novel and approved prior to the 18 June 1997 date established by the amendment to 90/220. Council Regulation (EC) No. 1139/98 (European Parliament, 1998) was established to replace the ad hoc measure Council Regulation 1813/97. It addresses the mandatory labelling of certain foodstuffs produced from GMOs, where certain foodstuffs are those containing DNA resulting from genetic modification techniques, instead of the protein requirement outlined in the Novel Foods Regulation. It supported earlier efforts to develop mandatory labelling requirements for the consumers' right to know. The regulation claims that mandatory labelling requirements are "necessary to ensure that the final consumer is informed of any characteristic of food property, such as composition, nutritional value or nutritional effects or the intended use of the food, which renders a food or food ingredient no longer equivalent to an existing food or food ingredient". In other words, this labelling legislation was increasingly shifting to the social rationality paradigm, although it maintained the substantial equivalence principle.

Regulation 1139/98 requires harmonised rules for the additional and specific labelling of foods and food ingredients produced from GM soya or maize, and that still contain GM DNA or rDNA. Under the regulation the following indications must appear on the label[4]:

1. 'produced from genetically modified soya (maize)' where the product consists of more than one ingredient
2. 'contains ingredients produced from genetically modified soya (maize)' where an ingredient is designated by the name of a category

However, the statement that a product 'may contain GM material' was determined to be unacceptable.

[4] From legislative summary: www.europa.eu.int/scadplus/leg/en/lvb/121090.html

Similar to both the directive 90/220 and the Novel Foods Regulations, the Soya/Maize regulation does outline possible exemptions from harmonisation. For instance, it permits Member States to unilaterally derogate from the requirements in order to protect human health, the environment or industrial or commercial property.

At the 21 October 1999 meeting of the European Council's Standing Committee for Foods, two notable amendments to the Soya/Maize regulation were approved (World Food Law Monthly No. 19, 1999; EU Food Law Monthly, 1999). First, with respect to labelling, the official EU policy on mandatory labelling is for the consumer right to know about the presence of GM material in food products. Key to such a mandatory labelling regulation is the tolerance level for 'adventitious contamination' which is the acceptable presence of a maximum amount of detectable GM material where over that amount a product would have to be labelled as containing GM material. The Committee approved a 1% tolerance threshold and a commitment to review the tolerance level as new detection technology is developed and comes into use. These were approved with a vote of 14/15 in favour (with one abstention, Spain). The European Parliament was dissatisfied with this Committee's approvals for two reasons. It wanted to see the regulation establish a specific risk assessment procedure attached to labelling approval and it pursued a 0.1% threshold level (European Parliament, 1999); a level also supported by non-governmental environmental organisations such as Friends of the Earth. Inversely, the Confederation of Food and Drink Industry wanted a 02% threshold level. By comparison, Japan recently approved a mandatory labelling law with a tolerance threshold of 05% of adventitious contamination.

The second amendment to the Soya/Maize regulation was the addition of GM derived additives and flavourings included under the mandatory labelling scheme (EU Food Law Monthly, 1999). This proposal was approved with a vote of 12/15 (with two against; France and Spain and one abstention; Ireland). The key to this amendment is that GM derived additives and flavourings must be labelled if they:

1. are, contain or consist of GMOs;
2. give rise to particular safety (allergy) or ethical concerns;
3. are not equivalent to their conventionally produced counterparts (i.e. when containing protein or DNA resulting from genetic modification); and

4. are used in 'sufficient quantity' where sufficient quantity is likely to mean 01% threshold of adventitious contamination as well (European Parliament, 1999).

In this sense, the regulation is entirely focused on the process and production methods of the final food products.

Council Directive 94/114/EC (Amended 70/524/EC)

DG VI has also developed product legislation relevant to agricultural biotechnology. First is the development of a Novel Feeds Directive, under the Council Directive 94/114/EC outlining the measures governing the proper use of animal feeds. The motivation for this legislation is derived from the fact that over 80% of the soya imported into the EU goes into animal feedstuffs and given the significant proportion of soya that is GM, it is clear that animal feedstuffs include GM soya along with non-GM soya. The amending regulation 70/524/EC introduced new categories of feed additives including feed containing or consisting of GMOs. This legislation is unique because it is a process or technology-based regulation implemented in a vertical regulatory agency.

Second, DG VI is developing a Novel Seeds Directive which is a proposed product legislation pertaining to the release of GM agricultural crops. Decision 94/730/EEC established simplified procedures for the release of GM agricultural crops, while Commission Directive 98/95/EC of 14 December 1998 established terms and conditions for the Community wide seed registry for GM varieties of crops in official categories.

EU Regulatory Administration

Administratively, DG XI is the responsible institution for the horizontal regulations 90/219 and 90/220, including all amendments. In reality, DG XI is the dominant actor in the EU regulatory approach and hence, it is reasonable to assume that Community consumer and environmental protection will remain crucial regulatory objectives despite the competitiveness pressures from DG III, VI and XII.

Along with DG XI, the regulatory role of DGXXIV has also increased. The Consumer Policy and Health Protection Directorate administers the relevant consumer health and scientific committees which advise in regulatory development. The relevant expert advisory committees for GM crops issues include:

1. Scientific Steering Committee, which oversees all of the expert scientific advisory committees;
2. Scientific Committee for Foods;
3. Scientific Committee for Plants;
4. Scientific Committee for Animal Nutrition; and
5. Scientific Committee for Pesticides.

For instance, the Scientific Committee on Plants is responsible for the technical issues relating to plants for human or animal consumption, production or processing of non-food products as regards characteristics liable to affect human or animal health or the environment, including pesticides. The Directorate's Consumer Action Plan 1999-2001 has four objectives. First, the development of a community-wide scientific basis for regulatory development under recognised risks. Second, when risk are unknown, regulatory development should employ the precautionary principle. Third, regulatory development must involve consultation with the Institute for Health and Consumer Protection. Fourth, food safety policy should include broader social and ethical considerations. The problem with first two objectives is their ambiguity. They do not specify the type of unknown risk, hypothetical or speculative. If the focus is on unknown but hypothetical risks, then the subsequent interpretation of the precautionary principle would be the scientific one. On the other hand, if the focus is on unknown but speculative risks, then the interpretation of the precautionary principle would be the social one. The remaining two objectives address 'social dimensions'.

Both DG III and DG VI remain responsible for their relevant product legislation, however, as was shown with the amendment to 90/220 following the Novel Foods regulations, DG XI's horizontal directives must be considered as dominant to the vertical product legislation.

The European Parliament must be considered as an increasingly important actor in EU regulatory development as well. For instance, in 1998, the Parliament voted 407 to 2 to censure the Commission's approval of a European variety of GM maize and to suspend imports of all GM maize. In late 1999, the Parliament Environment Committee Chairperson, Caroline Jackson, released a resolution (14 December, Strasbourg) calling for joint EP and Council of Ministers decision-making power on issues pertaining to GMO regulations. The basis is that the Parliament is the only directly elected body which gives it authority over issues of public concern.

However, like other EU development, this resolution further politicises the issue of food safety in the EU.

All the directorates are subject to the advice and guidance of various committees (Nature Biotechnology, 1996). Community rules on consumer protection and food safety issues are subject to the advice of the Scientific Committee for Food. Established under Commission Directive 97/579/EEC (European Commission, 1997), this committee is charged with providing excellent, independent and transparent advice to the Commission. The committee must be consulted on consumer health and food safety issues by the Commission. However, the committee may also, on its own initiative provide advice to the Commission on regulatory issues considered within its remit.

Along with the Scientific Committee for Food is the Advisory Committee for Foodstuffs established under Commission Decision 80/1073/EEC (European Commission, 1980). The Advisory Committee is charged with ensuring the close co-operation between the Commission and all relevant Community stakeholders in food law issues. Similar to the Scientific Committee, the Advisory Committee is either consulted by the Commission, or it provides the Commission with advice on issues relating to the harmonisation of all foodstuffs legislation. The fact that the Advisory Committee was established two decades ago, indicates the commitment of European food legislation to the whole range of consumer interests and concerns. An important difference with the Scientific Committee is that the Commission is not legally required to consult the Advisory Committee, because the advice is not considered to be independent like it is with the Scientific Committee.

Member States' scientific bodies may also provide advice and guidance to the Commission on issues of food legislation through the framework established by Council Directive 93/5/EEC (European Commission, 1993). The competent national authority must send to the Commission a list of institutes in the Member States that may provide technical assistance in areas including biology, mircobiology, biotechnology and novel foods and processes, methods of analysis, risk assessment techniques.

Current Regulatory Developments in the EU

On 23 February 1998, the Commission presented a proposal for a European Parliament and Council Directive again amending Directive 90/220 (European

Commission, 1998). The aim of the proposal is two-fold. First, to make the procedure for granting consent to the placing on the market of GMOs more efficient, certain and transparent for industry. Second, to make the procedure more accountable and open, including greater public access to the decision-making process, in order to build public confidence.

There are several industry-oriented proposed revisions. First, the proposal provides for the establishment of harmonised Community-wide methodologies for risk assessment for environmental release; currently under the discretion of the rapporteur country. Key to this harmonised risk assessment is the specification of two categories of releases. Category I releases are those, in compliance with Annex V, for which there is sufficient knowledge about the safety for human and environmental health and if the release is similar to previously approved releases that have not shown evidence of risk. Notification would be made only to the competent authority of the releasing Member State and an annual register of all Community-wide notifications for Category I releases would be published. Under the proposal, the competent authority must respond to the Category I notification within 30 days, however, it is unlcear whether or not the notifier must await formal consent before release. Category I releases resemble an approval fast-track procedure, similar to the USDA's non-regulated status. Category II releases are for GMOs for which there is not sufficient prior risk information or regulatory experience. Second, the proposals also include clarifying the type and quantity of technical information required for an application such as personnel training and supervision, monitoring schemes and emergency response plans. Third, timetables for either approving or rejecting applications are set out, in order to prevent the endless regulatory hold-up that currently burdens the approval process of GM crops. Fourth, the duplication of regulations under both horizontal and vertical regulations is to be removed, so that a risk assessment performed for one, is acceptable for the other.

There are also several proposed consumer confidence-oriented revisions of 90/220. First, is to include a fixed time market approval period, after which approval would have to be renewed. A current time period under consideration is seven years. Second, a potential revision is the compulsory monitoring of all approved products. Third, the proposal includes a mechanism to allow approvals to be modified, suspended or terminated where new risk information becomes available. Fourth, approvals by the Commission could be overturned by the Council of Ministers by a

simple majority vote on the recommendation of the relevant scientific committee, such as the Scientific Committee for Food. In fact, the proposals include mandatory consultations with the Scientific Committee for Food prior to any Commission approval. Fifth, the proposed amendments include a provision for full legal liability legislation for damages caused to human or environmental health. This was proposed because several Member States have developed or are developing their own liability laws for the environmental release of GMOs in order to create a credible incentive for private firms to minimise the release risks. Sixth is a proposed amendment to make consultations with the EU Ethics Committee and the broader public mandatory prior to any approvals.

The proposed amendments to 90/220 attempt to strike a very delicate balance. On one hand, they seek to create a streamlined, stable and certain regulatory process with a scientific basis on hypothetical risk and the removal of regulatory duplication. On the other hand, despite the attempts to establish a rules-based approach, the approval process has also become more politicised with Parliamentary voting for approvals and Council voting for the withdrawal of approvals. But can regulations be everything to everyone?

On the 11 February 1999 the European Parliament approved the proposals with 68 amendments. The amended proposal was presented to the Council for the establishment of a common position on 26 March 1999 (European Commission, 1999). These proposed changes are indicative of the politicisation of the biotechnology issue and the desire to regulate agricultural biotechnology according to its social dimensions.

More recently, EU environment ministers claimed that they have agreed on several aspects of the proposed amendments. First, they are all in favour of eliminating the fast-track procedures proposed under the dual category notification requirements. Second, they want a negative list of GM applications that can never be approved in the EU, including GM crops that use antibiotic resistant marker genes. Third, they have agreed to a moratorium on new commercial authorisations of GM crops while amendments to 90/220 are being made. Some Members, such as Denmark, France, Greece, Italy and Luxembourg argue that the moratorium should remain at least until amendments can be transposed into Member State legislation, a process expected to take until 2002 (Financial Times, 25 June 1999). Other Members have been hesitant to endorse this position because of concerns over its legality both at

the European Court of Justice and at the WTO (Independent, 25 June 1999). Recall, the position of the Environment ministers is crucial, because DG XI is the co-chef de file of the Directive and will take the amendment to the Council Committee of Environment Ministers for approval. However, from a commercial perspective, regardless of the official status of the moratorium, there is in essence a de facto ban on approvals anyway because there is currently not enough support in the European Council for a majority approval. Further, once the Ministers have agreed to the reforms, the amended legislation will then be put to the European Parliament for endorsement before it can become community law (Financial Times, 24 June 1999). The European Parliament included 39 amendments to the proposed directive most of which were accepted by the Commission in the fall 1999.

In January 2000, the EU Council of Ministers released its 'Common Position' on the various amendments to the directive 90/220, although France, Ireland and Italy abstained from the Common Position (AgraFood Biotech No. 20, 2000). The Council accepted all proposals from the Parliament including some which were not accepted the Commission. Of particular note is acceptance of the Parliament's interpretation of the precautionary principle (Article 17) which is essentially a legal definition of the social interpretation. The Common Position also indicates that an EU export and trade position will not be defined until after the January negotiations of the Biosafety Protocol (see Chapter 4.2) in order that the directive is consistent with international agreements. This is an important development because the EU trade position is explicitly linked with an international environmental agreement, rather than a trade-oriented framework supported in North America.

With respect to mandatory technology-based labelling rules for products derived from GM material, Community sectoral legislation for GM seeds, animal feeds, and pesticides are being developed in order to extend the mandatory labelling requirements into a more comprehensive framework based on the consumers' right to know.

An alternative to the mandatory labelling of products that contain GM material, is the Community-wide development of a voluntary labelling scheme for organically produced products. Indeed, despite the controversy associated with the mutual exclusivity of organic and GM crops the Commission is pursuing 'organic' as an alternative to foods that may have been produced from GM crops. The Commission is currently developing a certification framework, in light of the consumer concerns

with GM crops, to ensure that the organic label is used properly and consistently. The EU approach is based on Council Regulation 2092/91 which defines when farm produce may be labelled as organic and when produce may carry an EU organic quality mark or label. This regulation was amended in November 1992 Council Regulation 3713/92 requiring an inspection certificate to accompany organic food imported into the EU. This raises important trade issues when the definition of 'organic' means something different in another regulatory jurisdiction.

There are also two proposed EU institutional arrangements that could each play an important role in the regulatory system governing GM crops. The first is the European Foods Standards Agency (EFSA) and the second is the European Veterinary and Phytosanitary Inspection and Control Agency (EVPICA). The EFSA remains a vague proposal and the scope and depth of its regulatory authority currently remain unresolved. On one hand, some argue that it must be a transparent European institution with real regulatory power and transnational decision-making ability (EU Food Law Monthly No. 95, 1999). Others argue instead that it should be a forum for reconciling differences in Risk Analysis between Member States, but not a substitute for independent Risk Analysis in the Member States. The implication of this is that politics will remain inextricably linked to the development of food safety and environmental protection legislation in the EU. In fact, with respect to the proposed EFSA, the EU food safety commissioner David Byrne recently noted that responsibility for political decisions such as the detail and application of the precautionary principle, will remain with politicians (Eurofood, November 1999). Of course, according to the social interpretation of the precautionary principle, precaution is a political decision however this is in contrast with the scientific interpretation of the precautionary principle employed in North America which attempts to disentangle precaution for safety from precaution for political reasons.

The second proposed institutional arrangement which would have significant influence over GM crop regulations is the European Veterinary and Phytosanitary Inspection and Control Agency (EVPICA) (Horton, 1997). The objective of the EVPICA would be to enforce EU regulations in the plant and animal health fields. The new agency, already approved by the Council, would be located in Ireland and would take over the present inspection activities of DG-VI in other member states and in countries who export to the EU. Like the European Medicines Evaluation Agency

in London, the new EVPICA would be independent of other European Institutions such as the Commission or the Council.

In the fall 1999, the Commission proposed a Draft White Paper on Food Safety indicating the political priority that food safety has become on the European regulatory agenda. Indeed, it can be expected that the White Paper on Food Safety will represent a strong European food safety message in order to gain public confidence in the regulatory system. For instance, among the notable public-oriented proposals of the White Paper are:

1. the creation of a European Food Safety Agency;
2. changes to the system of scientific advice from the various advisory committees;
3. increased and mandatory traceability in the entire European food chain; and
4. the creation of a rapid alert food hazard warning system.

With respect to the creation of a EFSA, as previously discussed, the scope and the depth of the agency remain undecided and a bit controversial. For instance, it has been noted that the consumer directorate (DG XXIV) is not keen on an independent agency with real authority as it would overlap the consumer directorate's jurisdiction (EU Food Law Monthly No. 95, 1999). With respect to the changes to the standing advisory committees, these committees are currently composed of officials from member states who vote on key food issues pertinent to their particular remits. The proposed changes would see the creation of a single standing committee for all food issues, or at most two standing committees (food and animal nutrition & health).

An important EU regulatory development with respect to the market access of GM crops occurred in late 1999. The EU Environment Commissioner (DG XI), Margot Wallstrom, signalled that she would ask EU member governments to break the de facto EU moratorium on GM crop approvals and authorise 18 GM crop varieties currently help-up in the EU regulatory system. The condition on the approvals is that the applicant Life Sciences firms must voluntarily agree to adhere to the proposed amendments to directives 90/220, 258/97 and 1139/98 even though they have not yet been enacted. In fact, the Life Sciences firms have readily accepted the conditions (EU Food Law Monthly No.95, 1999). If member governments fail to agree to lifting their unilateral bans, then the EU may find itself compelled to take legal action against the bans, which is not a desirable situation.

There are several areas where further EU regulatory development is likely to occur. First, it may be expected that the Soya/Maize Regulation will be extended to apply in full to all GM crops commercialised in the EU. Second, given the unilateral Member State action, it is likely there will be pressure for the development of a centralised regulatory review-process although the extent that risk assessment and risk management are both centralised at the EU level remains unknown. Third, an important aspect of a mandatory labelling policy is the clarification of acceptable, standardised and accurate test methodologies for adventitious contamination. As well, standardised enforcement and monitoring protocols must be established.

7.3 Agricultural Biotechnology in the United Kingdom

In this section is an examination of the regulatory approach of the United Kingdom because it has experienced the most recent and dramatic rise of consumer concern about GM crops and subsequent pressure to adapt the regulatory approach to social issues.

7.3.1 The United Kingdom

The regulatory approach to biotechnology in general and agricultural biotechnologies in particular in the UK had initially been very proactive and appeared to be effective at balancing technological progress with precaution. Despite the apparent effectiveness, the regulatory approach has been heavily criticised by social interests such as consumer and environmental organisations, generating public doubt about its ability to protect consumers and the environment. In fact, it will be argued that social interests have pulled the UK regulatory approach off its initial scientific rationality trajectory and towards a social rationality trajectory. The result has been the creation of significant regulatory instability in the UK.

There are two sections to this discussion. First is an examination of the evolution of the UK regulatory approach and a discussion of its current structure. Second, is a simultaneous examination of the dramatic rise in consumer concerns about GM crops in the UK and the regulatory changes and proposals that have come about because of the dramatic rise in concern and opposition.

A. UK Regulatory Approach

The first UK advisory group for biotechnology regulations was the Genetic Manipulation Advisory Group (GMAG), established in 1975. The GMAG was under the jurisdiction of the Department of Education and Science and was responsible for monitoring research involving genetic modification techniques. The GMAG had focus on self-regulation (Patterson, In Press). The primary contribution of the GMAG was to establish a 'graduated' risk assessment scheme for various types of rDNA research (Ager, 1990). The GMAG employed the scientific interpretation of the precautionary principle in an attempt to balance the need for control and the need for continued research. For instance, hypothetical risk assessments were precautionary in the sense that the parameters and assumptions about risk were deliberately risk averse, to ensure that they over-estimated risk. The GMAG relied upon a network of local biological safety committees to assess the risks of and to monitor rDNA experiments conducted within their jurisdictions.

The first regulatory oversight was under the Health and Safety at Work Act (HSW) 1974, which had general provisions that employers take those actions as reasonably practicable to protect employees and the environment. The Health and Safety Commission (HSC) of the Health and Safety Executive (HSE) are the responsible agencies for ensuring that the provisions of the HSW 1974 are adhered to. In 1978, the Health and Safety (Genetic Modification) Regulations were developed under the authority of the HSW 1974. The regulations called for the mandatory notification for all contained genetic modification work to the Health and Safety Commission (HSC). These regulations continued the initial scientific rationality trajectory of GMAG.

In 1984, the GMAG was disbanded and replaced by the Advisory Committee on Genetic Manipulation (ACGM) under the authority of the Health and Safety Executive. The ACGM, although not under the direct jurisdiction of any government department, provided advice and information on technical and scientific safety issues associated with biotechnology. The ACGM developed guidelines for those researchers employing genetic manipulation techniques through working groups chaired by an ACGM member and composed of 'specialists'.

In 1989, the HSC issued new genetic manipulation regulations in order to deal with the imminent environmental release of GM material. The relevant regulation is under Part VI of the Environmental Protection Act 1990. The basis for the Act was the Royal Commission on Environmental Pollution, Chaired by Lord Lewis (Royal

Commission on Environmental Pollution, 1989). The Act set provisions for the establishment of the Advisory Committee on Releases to the Environment (ACRE) which is a statutory and independent committee of experts appointed by the Secretary of State. ACRE provides advice to the HSE and the relevant government departments and agencies on the environmental and human health and safety issues relating to the deliberate environmental release of genetically modified organisms[5].

In 1991, the UK-based Council for Science and Society released its expert panel report on the benefits and risk of genetically engineered organisms (Fincham and Ravetz, 1991). The Council was established in 1973 to provide independent and authoritative expert advice for policy-makers and the public on the implications of scientific innovation on society. The report concluded that UK regulations had effectively managed scientific progress with social precaution; "the effectiveness of a proper attitude is confirmed by recent experience of planned releases. Where public concern has been respected, as in this country, there have been no problems; elsewhere the record is mixed" (Fincham and Ravetz, 1991). Of course, by the late 1990s this conclusion was proven to be too premature.

The Deliberate Release Regulations under the Environmental Protection Act were amended in 1992 (SI 1992/3280) and 1995 (SI 1995/304) in order to transpose EU Directive 90/220 into UK legislation. These modifications required environmental risk assessment, notification, and consent from the Secretary of State for Agriculture prior to the release or marketing of GMOs. An advisory committee of scientific and medical experts, the Advisory Committee for Novel Foods and Processes (ACNFP) advises the Secretary of State on applications for consent.

In November 1994, the UK government held public consultations on plant biotechnology, administered by an independent steering committee established by the Science Museum, in order to gauge the social dimensions of biotechnology. The participants chose the questions to ask and the experts to pose them to. The final report was published through the British Biotechnology and Biological Sciences Research Council (Science Museum, 1994). The public technology assessment dealt with a wide range of concerns from human and environmental health and safety to socio-economic impacts, ethical and moral implications (Madden, 1995).

[5] See www.environment.detr.gov.uk/acre

Currently, the UK regulatory approach involves both the Department of the Environment, Transport and the Regions (DETR) and the Ministry of Agriculture, Fisheries and Food (MAFF). The approach is co-ordinated by the Cabinet Sub-Committee on GM Technology. In order to release GM crops for field testing, a Deliberate Release Form must be secured from DETR who receives advice from the ACRE . The cost of each application is £3000. An application can be renewed or varied for a £700 fee, however, a variation cannot include a change in the size of the field trial or in the duration of the field trial. A recent Field Trial Consent for the planting of a herbicide tolerant rapeseed was revoked because it was found to have contravened the conditions of the variation process. Agrevo, the applicant firm, applied for, and received approval for the variation of a previous field testing consent. But Agrevo should have filed for a new Field Trial Consent, because the intended variations were both to increase the size and duration of the trial (Times, 18 September 1999). Also providing environmental advice is English Nature, a government advisory body on general wildlife issues.

For commercial approval to use a GM crop in the food supply, the firm must apply to MAFF while the application is considered by the Advisory Committee on Novel Foods and Processes (ACNFP), which is the UK Competent Authority. This is the UK transposition of the Novel Foods Regulation 258/97. If the GMO is to be marketed alive or viable (e.g. a GM tomato) then additional approval must also be secured from the DETR, which is the UK transposition of the 90/220 Directive. In January 2000, the ACNFP and the Advisory Committee on Animal Feedingstuffs (ACAF) held a joint meeting to examine the overlap of their respective remits with respect to assessing novel foods and novel feeds, particularly GM foods and feeds. They agreed to develop complementary assessment approaches.

Finally, the labelling of novel products and products derived from GM material is under the jurisdiction of the Food Advisory Committee (FAC). In 1983, the Food Advisory Committee (FAC) chaired by Sir Colin Campbell, concluded that there was no justification to insist on labelling from a safety point of view, and it did not support labelling for the consumer's right to know. Initially, the ACNFP was responsible for establishing UK labelling requirements for GM products according to the EU Novel Foods Directive. However, in early 1999, this responsibility was passed to the Food Advisory Committee. Anti-GM critics claimed that this proved the lack of expertise of the ACNFP, and thus signalled the incompetence of the UK regulatory

system (Wadsworth, 1999). On the contrary, however, this was a reasonable decision because the remit of the ACNFP is to ensure the safety of novel foods, not to establish labelling policies predicated on the consumers' right to know. Indeed, the former activity is a risk assessment function while the latter is a risk management function and the two should have been separated. In 1998, the UK developed a voluntary labelling scheme for producers to label foods containing GM DNA. In 1999, the government announced the schedule for mandatory labelling of food produced with GM material. Food retailers, such as supermarkets had to label the presence or possible presence of GM material as of 19 March while restaurateurs, café owners and landlords (e.g. pubs) had to do the same by 19 September 1999.

In 1997, the Centre for the Study of Environmental Change at Lancaster University argued that the UK regulatory approach "appears to be failing to reflect important public concerns arising from acknowledged uncertainties and unknown potential risks from the technology (however low their probabilities)" (Grove-White *et al.*, 1997). To remedy this situation, it was suggested that the UK must actively consult the public through, for example, statutory obligations and that the Risk Analysis framework must be replaced with broad consultations based on ascertaining the social intelligence, not the scientific intelligence of risk.

The UK was the first country to approve a genetically engineered organism for use in the food supply (Harlander, 1993). The approval, in March 1990, was for a strain of bakers yeast (*Saccharomyces cerevisiae*) that produces elevated levels of carbon dioxide. Further, this GMO was determined to be substantially equivalent, hence, there were no labelling requirements. More specifically, with respect to approved GM crops, three varieties of GM crops have been approved including one GM variety of herbicide tolerant rapeseed and one GM variety of herbicide tolerant soybean and one GM variety of tomato have been approved for commercial release in the UK by the Department of the Environment on the basis of advice provided by the ACFNP[6]. The GM soybean, approved in 1994, was Monsanto's herbicide tolerant 'Round-up-Ready' variety. The basis for these approvals was very much the scientific rationality approach.

Yet, following the scientific rationality approach, the ACNFP has also rejected a commercial application for a GM maize. The Commission approval for Ciba-

[6] Regulatory Developments in Biotechnology in the United Kingdom: www.oecd.org/ehs/ukreg.htm

Geigy's (now Novartis) GM maize was rejected in the UK by the ACNFP, even though it had been approved by the rapportuer country, France. The ACNFP rejected it over concerns regarding the use of the antibiotic resistant marker gene. The GM crop was rejected outright because it was felt that this was a safety issue, at least a secondary safety issue, in the sense that the use of antibiotic resistant genes in crops could add to the growing antibiotic resistance of pathogens harmful to human health. The ACNFP concluded that the GM maize was safe for use in food products where the GM DNA and protein would be processed out, however, with respect to use as a raw animal feed, there was recognised uncertainty about the safe use (ACNFP, 1995). Labelling was considered insufficient because antibiotic resistance affected all and was not a consumer choice or right to know issue. Despite this concern in the UK, the EU Scientific Committees for Food and for Animal Nutrition both assessed the risk as remote or virtually zero and approved the GM Bt maize for use in the food supply and as an animal feed. Labelling was insufficient because antibiotic resistance affected all and was not a consumer choice or right to know issue[7].

There are two important developments in the UK regulatory approach. The first development is the formation of an industry association designed to proactively deal with consumer concerns about GM crops. The Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) was informally developed in 1997 and formally established in June 1998. The three main objectives of the SCIMAC are to:

1. establish industry-wide protocols (Codes of Practice) for best practice in the commercial introduction of GM crops;
2. provide practical guidance to growers on the management of specific agronomic traits, such as herbicide tolerance; and
3. maintain an active and open dialogue on GM crop issues with other interested parties.

SCIMAC is composed of farmers, seed traders, agro-chemical firms, plant breeders and biotechnology firms and its creation was driven by the exogenous rapid adoption of GM crops in North America and the endogenous lack of public confidence in the UK regulatory system. The intent is to find the equitable balance in regulatory

[7] See: Scientific Committee for Food (1996) Opinion of the Potential for Adverse Health Effects from the Consumption of Genetically Modified Maize. Expressed on 13 December 1996; and Scientific Committee for Animal Nutrition (1996) Report of the SCAN on the Safety for Animals of Certain Genetically Modified Maize Lines Notified by Ciba-Geigy in Accordance with Directive 90/220 for Feedingstuff Use. Expressed on 13 December 1996.

approach between an industry led approach and a overly precautionary approach of most GM critics. The approach is based on the successful 30 year programme of preserving the purity and quality of certified seed. In other words, the need to preserve the identify of crops is not a new phenomenon, and sophisticated and successful strategies to achieve this have been in place for decades although the public were not aware of this. To date, several SCIMAC initiatives are worth noting. First, it has announced a voluntary moratorium on the commercial release of GM crops until such time as the government regulators have fully assessed the field trials for safety. Second, SCIMAC has developed a Code of Practice on the Introduction of GM crops for both field-testing and the future commercial release. Third, it has proposed a farm-scale ecological monitoring programme comparing GM and non-GM crops in intensive agricultural system in order to address the concerns of the most vocal anti-GM critics. This programme would be jointly administered by the DETR, MAFF, English Nature and the Royal Society of Plant Breeders.

The second important development in the UK regulatory approach is the imminent establishment of the Food Standards Agency (FSA). The FSA emerged out of the BSE crisis as an attempt to institutionally separate the functions of consumer protection and industry promotion. A public body of 12 independent members from public interest backgrounds will govern the FSA in an open, transparent and consultative fashion. The regulation of GM crops will fall under the jurisdiction of the FSA, rather than under the jurisdiction of DETR and MAFF. The FSA will implement and assess the safety of novel foods and processes and have approval authority over releases into the environment.

B. UK Opposition to GM Crops and Regulatory Responses

As a result of recent public resistance to GM foods, the UK regulatory approach has been reformed and amended in an attempt to stem the public concern. The opposition in the UK is extremely polarised with social interest organisations such as Friends of the Earth and the Soil Association arguing that there is no middle ground; the government must choose either GM crops or organic production. The key point is that the recent public resistance and put pressure on the UK regulatory approach to shift towards a social rationality approach.

Much of the public concern appears to have risen from claims made by Dr. Arpad Pustzai in August 1998 about the damage which GM potatoes had caused to the

health of rats. Dr. Pustzai, a researcher at the Aberdeen Rowett Institute, was researching the effect of GM potatoes, engineered with a lectin protein from the snowdrop plant, on the health of rats. This research effort was driven by an apparent lack of scientific evidence on the health affects of GM crops. The early research results, reported by Dr. Pustzai, were that the GM potatoes damaged the immune systems, stunted the development of internal organs and led to defective brain development in the rats. After reporting his preliminary conclusions, Dr. Pustzai faced harsh criticism from the government, the Rowett Institute and from other scientists. The scientific criticisms were from those who believed that he broke the rules of scientific disclosure while the government felt that his preliminary comments undermined the public confidence in the regulatory approach. Dr. Pustzai's conclusions became the justification for a broad range of concerns about the consumer and environmental impacts of all GM applications, rather than just concern about the safety of GM lectin potatoes.

Concerns about GM crops have produced a range of reactions from cautious acceptance to outright rejection across a broad range of groups. Environmental organisations include Friends of the Earth, Greenpeace, Earth First!, This Land is Ours, English Nature, Gardeners GMO Group and the Royal Society for the Protection of Birds. Consumer groups include the Consumers' Association and Consumers' International. Other organisations include the Soil Association, Christian Aid, the National Federation of Women's Institutes and the British Medical Association. Also, notable opposition comes from both the Prince of Wales, a long-time supporter of organic farming practices, and the Independent Newspaper with its 'Stop GM Foods' campaign launched on 7 February 1999.

An interesting aspect of the opposition to GM crops or 'Frankestein Food' in the UK, is the portrayal of GM crops as 'Monsanto's science'[8]. Yet, some of the most advanced GM crop developers are European firms such as Agrevo (Germany), Astra-Zeneca (UK), Hoechst (Germany), Novartis (Switzerland) and Rhone-Poulenc (France). In fact, the most controversial EU approval was for Ciba-Geigy's (Novartis) GM maize and the 'illegal' field trials in the UK were undertaken by Agrevo.

[8] See especially Independent (12 October 1999) 'GM Foods: The Debate, A Special Report Produced in Association with Iceland'; and also Mail on Sunday (6 June 1999) 'Up with Prince Charles' Letter by Veronica Pride; The Express (18 September 1999) 'Sound Taste in Food'; Independent on Sunday (3 October 1999) 'The Humbling of a GM Giant' by Geoffrey Lean

In February 1999, the UK government announced the mandatory technology-based labelling of the presence or possible presence of GM material in a food product for food retailers and small food service establishments. Food retailers, such as supermarkets had to label the presence or possible presence of GM material as of 19 March while restaurateurs, café owners and landlords (e.g. pubs) had to do the same by 19 September 1999. While this was the UK's transposition of the EU labelling requirements, it was also importantly driven by the severity of the domestic opposition to GM crops.

Opposition to GM crops also came in the form of commercial threats to those producers who might seek to plant them. For instance, the Soil Association warned that producers would lose their organic certification. In fact, a field trial of Agrevo's GM rapeseed was destroyed by the farmer for this very reason (Metro, 8 June 1999). Also, the Institute of Chartered Surveyors advised farmers that growing GM crops could threaten the value of their land and put producers at risk of legal liability action in the event that environmental damage could be proven.

At the end of March, environmental protesters destroyed field trials of GM rapeseed in Devon, England. Such direct action occurred previously, in July 1998 in Oxfordshire, but was taken by a more radical environmental organisation GenetiX Snowball. The difference now was that the mainstream environmental lobby, not just the radical fringe, was willing to take direct action and destroy the field tests. For instance, Lord Melchett, the Chairman of Greenpeace was arrested for participating in the direct action. Lord Melchett defended the illegal action on the grounds that, basically, over a decade worth of lawful protest did not impose their beliefs on the regulatory approach and they were dissatisfied with this fact[9]. Despite the illegal destruction of GM crops and vandalism of agricultural lands, there has been little willingness for the authorities in the UK to seek prosecution against the 'eco-warriors'.

In May 1999, the Commons Environmental Audit Select Committee, an all-party committee examining environmental policies, recommended four immediate policy responses to the public concern. A moratorium on commercial plantings of GM crops, tighter rules on field trials, broader regulatory consultations encompassing

[9] The frightening extension of a 'Greenpeace Argument for Illegal Action' is its adoption by other groups, such as right-wing fascist groups, that illegal action is acceptable if ten years worth of protesting does not impose their beliefs on the regulatory approach.

ethical issues and more public funding of GM crop development to counter act the perception that it was a private technology (Financial Times, 14 May 1999; Independent, 14 May 1999). The basis for the recommendations was that the increasing public concern would create a loss of public confidence in the regulations. Therefore, in order to be socially responsive, this recommendation called for tighter regulations to assuage public concerns regardless of whether or not the concerns were driven by speculative risks.

In defence of the scientific UK regulatory approach, Profs. Janet Bainbridge, Chair of the ACFNP and John Beringer Chair of the ACRE testified to the Commons Science and Technology Committee that a ban on the field testing or commercial cultivation and sale of GM crops would not increase consumer and environmental safety. Instead, its only impact would be to severely impact the competitiveness of the UK GM technology industry (Independent, 18 March 1999).

In May, a government review of the UK regulatory approach was released. The review was authored by England's Chief Medical Officer Prof. Liam Donaldson and by Sir Robert May, the government's Chief Scientific Adviser. The review concluded "there is no current evidence to suggest that genetically modified technologies used to produce foods are inherently harmful" (Financial Times, 22 May 1999). However, it also called for the creation of two new advisory committees and a National Surveillance Unit to rebuild confidence in the regulatory approach. The two new advisory committees are the Human Genetics Commission and the Agricultural and Environment Biotechnology Commission. The key feature of there two new advisory committees is the deliberately broad participation base. The National Surveillance Unit is proposed to monitor the long-term health and nutritional impacts of GM material in the food supply. Critics of the review included the Consumers' Association, which raised concerns about the review's failure to deal with long-term risks, the British Medical Association and the Friends of the Earth, which called the report "miserably inadequate"(Daily Telegraph, 22 May 1999).

Also in May, the Royal Society, the UK's senior scientific academy, announced that the independent review by six scientists of Dr. Pustzai's research found that the conclusions claimed were not supported by the evidence. The Royal Society report concluded that the research was "flawed in design, execution and analysis" and that there was "an incorrect use of statistical tests". It also concluded that no conclusions could be drawn about the safety of GM foods, in general, from

research on one animal species, one type of food, one type of gene and one genetic transfer technique. Further, the report noted that the difficulty with scientific innovation is that "nothing can be absolutely certain in a field of rapid scientific technological development". Yet, this uncertainty has given rise to public fear which has "been echoed, and sometimes cynically distorted, by tabloid newspapers and special interest lobby groups"(Daily Telegraph, 22 May 1999; Independent, 19 May 1999).

In September 1999, Sir Richard Sykes (1999 President of the British Science Association) called for secret trials of GM crops in order to advance the technology while protecting it from direct, illegal action or vandalism. He argued that without the trials, Britain would fall behind in capacity and competitiveness.

In September 1999, Friends of the Earth successfully challenged the DETR over the field trial consent given to Agrevo for its GM rapeseed. Indeed, Agrevo had violated the conditions for when an applicant can make a variation to a Field Trial Consent, and when an applicant must make a new Field Trial Consent. When the illegal action was discovered, Agrevo had already planted three of four fields, and the intended fourth planting was put on hold. While admitting that Agrevo had violated the law, the Environment Minister (Michael Meacher) argued the previous three trials should continue because it was a technical error and not a health and safety issue. The reaction by the Friends of the Earth was that the UK government was willing to bend the law to support biotechnology companies (Times, 18 September 1999; The Express, 18 September 1999). Yet, the UK government has 'bent the rules' to the benefit of critics as well, as it has not pursued legal action against protesters who destroyed legal field trials of GM crops.

Also in September, Friends of the Earth announced that research by the national pollen research unit, in Oxfordshire, UK, has revealed that pollen from GM crops can be found up to three miles away from the field test site. At issue is not the fact that cross-pollination can occur, instead, it is what kind of tolerance is demanded. In Chapter 5.1.6 it was noted that there exists controversy between those who support zero tolerance and those who support some minimum tolerance of risk. Friends of the Earth, along with the Soil Association, support a zero tolerance policy and regard the research findings as completely unacceptable. In defending the regulatory policies, Prof. Allan Gray of the ACRE acknowledged that there is a minimum risk of cross-pollination and that the field testing regulations were designed to minimise that risk to

an acceptable level, not to eliminate it completely. Further, he points out that safety is the real issue, and since the GM crop is safe, there is no safety concern if it cross-pollinates.

The latest development in the research of Dr. Pustzai was the announcement by the British medical journal, The Lancet, that it will publish the complete study on the affects of GM potato consumption on the immune system of rats. This has been heralded as a vindication of Dr. Pustzai's claims (Independent on Sunday, 3 October 1999). Yet, far from a vindication of Dr. Pustzai, this represents a triumph of good science and an example of why the scientific methodology must be used in dealing with risk assessment. It has been noted that "good science is difficult to achieve, and bad science is all to easily hyped into a scare story" (Independent, 19 May 1999). The original evidence of harm was based on incomplete and impartial research findings and was subsequently denounced by other scientists. In this case, Dr. Pustzai has provided The Lancet with the complete research which has been peer-reviewed and found to be credible. Yet, as noted by the Royal Society, the fact remains that this is research about one genetic transformation technique on a potato and from a specific plant (snowdrop) not currently used on any commercialised GM crops. It is not evidence that GM techniques in general are unsafe.

In October, the UK government announced an initiative to embark on broad participation negotiations on the future regulatory approach to GM crops, including the participation of consumer and environmental groups, the biotechnology firms and government (Independent on Sunday, 10 October 1999). In fact, regulatory development in the UK can be expected to be focused on assuaging public concerns about GM crops through the risk management procedure of Risk Analysis, rather than through the hypothetical risk assessment process. For instance, the regulatory negotiations are to be facilitated by the Environment Council with a view to finding common ground between the supporter and critics, a political balance.

On the 13 October 1999, the government announced that the ACNFP will routinely disclose non-commercially confidential information on novel foods under assessment on a web-site, prior to making its recommendations. Further, once an assessment is complete, there will be a public comment period before it is forwarded to the European Commission. This is development is aimed at enhancing the transparency of the assessment process and to ensure that the UK recommendation on novel foods reflects public concerns more fully.

On 5 November 1999, the UK Environment Minister Michael Meacher announced that instead of a ban on commercial plantings, a voluntary agreement with the GM crop developers and seed companies to resist commercial-scale plantings until 2002, at the earliest, had been reached. The industry was represented by the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), developed a 'Code of Conduct' for producers using GM crops. The Code of Conduct includes advice on the distances at which GM crops must be grown from either non-GM or organic crops. Further, these voluntary guidelines are underpinned by Technology Use Agreements between the GM seed companies and the farmers. This agreement allows for four full years (1998 – 2002) of field trial evidence to be collected and assessed. However, GM crops grown elsewhere, and approved as safe in the UK will be allowed to be imported and used in the food supply.

Therefore, the UK regulatory approach, initially on a scientific rationality trajectory, can be expected to focus primarily on the speculative risks fuelling public resistance to GM crops as it shifts to a social rationality approach. The implication of this shift is that as long as GM crops remain a highly politicised issue in the UK, the regulatory approach will remain unstable and unpredictable. The paradox is that attempts to answer the very questions about GM crops that the critics are basing their resistance on are being thwarted by vandalism in the name of 'direct action'. Indeed, it appears that the critics are willing to undermine due scientific process because of the threat that it will contravene their interests in the exact same way that they accuse multi-national biotechnology firms of doing.

7.4 EU-Member State Regulatory Integration

The EU-Member State strategy for regulatory integration, according to the 'new approach', is a strategy of deeper social integration blending regulatory co-ordination with regulatory competition. The basis of this strategy is the establishment of minimum essential requirements (MERs), harmonised across all Member States. For controversial issues, the minimum essential requirements may be decided by the Council of Ministers or by the European Court of Justice (Woolcock, 1996). An important feature then is that in the absence of agreement among all Member States, the EU MERs are top-down regulatory principles imposed on the Member States.

On this foundation, is a process of ex ante regulatory co-ordination through mutual recognition. This has been an effective strategy for removing the politics out of

many regulatory integration efforts, however, this strategy has not been successful in all areas, especially GM crops regulations.

When Member State regulatory action contravenes policy positions of the EU the European Commission may bring legal action against the member state in the European Court of Justice. The member may be ordered to pay fines for failing to comply with community rules. Lister argues, with respect to food safety regulations, that the European Court of Justice has made it clear that "by becoming members of the European Community, Member States had given up their sovereign authority to write food laws as they saw fit. Rather, they had only limited ability as member states to restrict marketing within the EU of foods so long as they meet minimum essential requirements" (Lister, 1992).

The possibility of Member State regulatory divergence has been exemplified by Austria and France who have both imposed unilateral bans on GM crops which have been determined to be unjustified at the EU level. For instance, Austria imposed unilateral bans on Ciba-Geigy's (Novartis) GM Bt maize in December 1996 and on Monsanto's GM Bt maize (MON810) in May 1999 on the basis of evidence presented to the European Commission's Scientific Committee for Plants. This evidence allegedly indicated a link between GM maize and environmental damage and the action was taken under Directive 90/220's Article 16. In October 1999, the Scientific Committee ruled that Austria's ban is not justified under Article 16 and Austria will be expected to lift the ban; although no time frame is set for this. Similarly, in an opinion, the ECJ indicated that the French ban on GM Bt maize is unjustified. Also, the recent French refusal to endorse the safety of British Beef despite the endorsements by Britain and the European Commission is indicative of member state regulatory divergence. When France first refused to lift their ban, the European Food Safety Commissioner (David Byrne) threatened legal action in the European Court of Justice. In response, French health scientists presented new proof to the European Commission's Scientific Experts and the 12 member BSE Working Group, that apparently supports their claim that British beef is still not safe. Faced with new evidence, the Commission stepped back from its legal action threat and announced that it would review the new evidence. The review concluded that the scientific evidence presented by France was insufficient justification for the continued ban. The intransigence of the French has led to doubts in Germany about the safety of British beef as the German Health Minister (Andrea Fischer) announced that Germany would

also review the new evidence before lifting its ban. So whose science is right? British beef producers, confident of the safety in their beef staged boycotts of French products and dock-side embargoes of French food imports, which were successful on the 11 October 1999. And ever responsive to commercial opportunities, UK supermarkets announced particular initiatives to show support for British farmers and to capture positive media attention, similar to their anit-GM positions. The UK-based National Farmers Union has suggested that the ban is nothing more than regulatory protectionism and that the "so called new evidence was nothing more than a sham, a charade and a complete work of fiction"[10].

In short, unlike the degree of regulatory integration between Canada and the US based on shared regulatory principles, regulatory integration between the EU-level and Member States is not necessarily a foregone conclusion because the approaches can differ significantly. For instance, the examination of the EU, the UK and the Danish regulations reveals that the EU regulations sit somewhere in between the regulatory approaches of the two Member States. The social interpretation of the precautionary principle in Denmark could easily produce domestically transposed regulations far more stringent and technologically precautious than found in the UK, despite the fact that they are based on the same EU directive. In this sense, it is inaccurate to think of the 'EU' as a homogenous regulatory jurisdiction. Instead, awareness of the limitations of EU-Member State regulatory integration is crucial.

7.5 Conclusions

The EU regulatory approach is summarised in Table 7.1. The most important point is that despite an initial scientific rationality trajectory, internal factors have caused the EU approach to shift to a distinctly social rationality trajectory built on the tradition of regulatory accountability or political control over discretionary regulatory decision-making. The dominant actors are DG XI and DG XXIV, the environment and consumer directorates, respectively. This means that social interests, the clients of these directorates, can be expected to exert more influence over the EU regulatory development process than economic interests. The regulatory belief is that with social regulations it is not possible to disentangle actual from perceived risks according to a scientific rationality paradigm. Instead, perceived risks are a legitimate regulatory

[10] Ben Gill, NFU President quoted in Times (9 October 1999) 'Climbdown on Beef Threatens Fresh Crisis' by Martin Fletcher and Valerie Elliot.

target despite the lack of scientific justification for such a perception. For example, in 1997 the EU approved GM maize initially approved by the rapporteur member, France. However, in the meantime, French elections brought in a new political administration less supportive of GM crops. The new Prime Minister overruled the recommended approval of the French competent authority, causing the chair of the authority to resign (Nature Biotechnology, 1997). Currently, four GM crops applications have been approved as safe by scientific committees but have been rejected by politicians fearful of the public backlash, should they endorse the GM crops[11]. In fact, in November 1999, EU member governments voted against the scientific approvals for commercial introduction. The vote was taken in an Article 21 committee and the rejection was based on a claim that more information was required (Public Ledger No. 72 139, 1999). It has been argued that in general, the perception of 'technocratic' decision-making in the EU is incorrect because social dimensions have been a significant part of biotechnology policy in the EU (Sclove, 1996). Landfried (1997) argued "the diverse mixture of national, supranational, technocratic and political interests within the Commission, Council, Parliament and committees". Moreover, it has been argued that GM crops have become enmeshed in the political and social world of European food politics where social interests exhibit relatively more policy power than in North America.

> *The process of* [food safety] *policy formation in Europe is a considerably more complex and nuanced system than appears to be the case in the USA. The power of vested interests and social democratic impulses makes the final policy position taken in Europe a far less scientific and rigid proposition than is expected in the Sanitary and Phytosanitary Agreement* ...[which] ... *contains a rather fundamentalist model of regulation that is out of kilter with the political economy of regulation in a European environment (Evans, 1999).*

And that, in general, "Europe has a history of prohibiting new food technologies that are used widely in America" (Economist, 14 September 1996).

Further, the EU regulatory approach is technology-based according to dominant horizontal regulations employing the social interpretation of the

[11] These crops include: Monsanto's GM sugar beet and Maize, along with two varieties of GM oilseed rape developed by Agrevo.

precautionary principle. For example, in May 1999 the Commission decided to freeze the approval applications of all GM Bt maize crops based on the release of the Cornell Butterfly Research results.

	Application	Status	Agency
Horizontal legislation			
Council Directive 90/219/EEC of 23 April 1990	On the Contained Use of Genetically Modified Micro-Organisms Covers any contained use of genetically-modified microorganisms (GMMs), both for research and commercial purposes; Annex I contained the crucial definition of biotechnology that made this a process-based, not product-based regulation	Implemented	DG-III & DG-XI
Council Directive 90/220/EEC of 23 April 1990 and Directive 94/15/EC	On the Deliberate Release of Genetically Modified Organisms into the Environment Covers experimental and marketing-related aspects of genetically modified organisms (GMOs), which covers any R and D release of these organisms into the environment and contains a specific environmental risk assessment for the placing of any product containing or consisting of such organisms onto the market	Implemented	DG-XI
Reg 258/97/EC, May 15, 1997	Regulation on Novel Foods regulates the placing on the market of foods and food ingredients for human consumption containing, consisting of, or derived from GMOs. However, Novel Foods Directive still granted 'essential equivalence'	Implemented	DG-III
Annex III of the 90/220 as amended 18 June 1997	Sets labelling and new information notification requirements for all new GMO approvals for putting products on the market in the EU. This annex superseded the Novel Foods directive by eliminating the essential equivalence, and making all GMOs subject to labelling.	Implemented	DG-XI
Proposed revisions to Council Directive 90/219/EEC, November 1997	Proposed that authorisations to place GMOs on the market, issued under 90/220, be valid for a period of seven years only; if the authorisation is not renewed after the seven-year period, the product must be withdrawn from the market	Pending, adopted by the Council of Ministers	DG-XI
Product legislation			
Council Directive 93/114/EEC, amending Directive 70/524/EEC	Feeding stuffs. This amendment introduced new categories of additives, including, among others, additives containing or consisting of GMOS into the existing legislation: the amendment will enter into effect as of 1 October 1994	Implemented	DG-VI
Decision 94/730/EEC	Establishing simplified procedures for the release of genetically modified crop plants (first simplified procedure)	Implemented	DG-VI
Directive 98/95/CE, 14 December 1998	Establishes terms and conditions for the registration of GMO varieties in official catalogues; specifies that GMO varieties must be indicated in catalogues	Pending	DG-VI

Table 7.1 EU Agricultural Biotechnology Regulations

The EU regulatory system also provides for wide actor participation in the regulatory decision-making to ensure that the social dimensions of agricultural

biotechnology have been addressed. It has been argued that in 1991, the development of EU agricultural policy was difficult because of the involvement of agriculture and budget, foreign and trade ministers (Phillips, 1991). With GM crops, consumer, environmental, technology and industry ministers can also be added to this mix, further complicating policy development. Also, labelling is based on the consumer's right to know whether GM material has been used in the production of all food and feed products, regardless if they have been approved as safe and substantially equivalent.

Given the mix of horizontal and vertical legislation, the breadth of regulatory participation and the uncertainty surrounding the many proposals for revision, the current EU regulatory framework for GM crops is enigmatic and unstable. Essentially, the EU is attempting to redesign the regulatory system to meet the spectrum of concerns from scientists and industry about R&D and competitiveness to the whole range of consumer interests and concerns. Further, it must do this with the highly politicised issues associated with agricultural biotechnology specifically and with the food safety and environmental issues in general. As a result, legislative amendments are made incrementally, while the regulatory principles remain in tact.

There are three important aspects of the EU regulatory approach to consider. First, the EU regulatory approach is unstable leading to significant commercial uncertainty. As social interests tend to hold the balance of power in the regulatory development process EU regulations are unstable as they react to perceived public risks in order to be accountable and socially responsible. Indeed, GM crop applications, approved in North America, in compliance with EU regulations and in fact approved by European scientific committees have been rejected by politicians leaving the application in a suspended state of regulatory hold-up.

Second, the EU approach has created a regulatory floor not a regulatory ceiling. That is, Member States, according to Article 130r Title XVI Environment of the Treaty Establishing the European Community, can and do unilaterally impose national regulations more stringent than corresponding Community regulations. For instance, the UK, France and Denmark have called a partial halt on GMO approvals, while France, along with Austria, Greece and Luxembourg have imposed unilateral bans on certain new crops. Austria has also imposed both a complete ban on the commercial release of GM crops and a complete ban on the patenting of life. This action was driven by a public petition endorsed by 20% of the electorate (Ho, 1998).

Yet, if Member State legislation is in contravention of EU law, then why doesn't the Commission challenge the legality of this action before the European Court of Justice? Several cases have indeed gone before the ECJ[12] but essentially the social rationality approach and the politicisation of the GM crops issue combine to ensure that although Member States are in contravention, the Commission simply lacks the political support to pursue regulatory integration through legal channels. The result is fragmentation of the Single Market and considerable uncertainty surrounding the approval of GM products in Europe. Therefore, while the European 'New Approach' was developed to specifically deal with the problems of mixing politics with regulatory development, it appears that with respect to GM crop regulations, the EU regulatory approach has shifted to a social rationality paradigm that necessarily mixes the politics of accountability and social rationality with the regulatory development process.

The third important aspect of the EU regulatory approach is that it appears to fail to meet either the demands of economic or social interests. Similar to the North American regulatory approach, the European regulatory approach may be assessed according to a commercial and a social perspective. From a commercial perspective, the European approach has failed to establish stable and certain regulations necessary for industrial development. Approval applications have been paralysed within the complex and time-intensive approval process frustrating GM crop developers and creating trade tensions. In fact, the European approach has sacrificed commercial objectives to meet social objectives. Yet, despite this effort, the regulators face severe criticism that they are too commercially-oriented. The result is that the European approach, while striving to find the middle, has instead produced a regulatory approach that fails to meet both commercial and social needs.

Given the regulatory difficulties, would EU food laws be better served as regulations rather than directives? Directives are developed and accepted at the EU level but then are transposed into the legal framework of each member state. In order to aide transposition, directives sacrifice detail in favour of general principles. The result EU regulatory instability as the legislation of member states can vary considerably. As an alternative, EU food regulations must be accepted 'as is' by member states and often are more detailed and specific allowing less possible

[12] A France ban on Novartis GM Bt Maize was ruled as unjustified in an opinion by ECJ Advoate-General Jean Michel, released in November 1999. The final ruling is expected in April 2000.

variation. This, of course, makes the development and negotiation of regulations more onerous, but they are explicitly efforts in regulatory co-ordination and once developed they yield both regulatory detail and stability.

In summary, Table 7.2 presents the regulatory checklist for the EU. The general interpretation is that the EU regulatory approach is predominantly congruent with the social rationality paradigm. This trajectory has come about since the late 1980s as the result of endogenous political economy factors in the EU. Further, this trajectory is in conflict with the regulatory integration approach supported in North America and by the international trade regime.

	Scientific Rationality	Social Rationality
General Regulatory Issues		
Tradition		✓ Regulatory Accountability
Belief		✓ Technological precaution: Socially responsive regulations increase public credibility and confidence
Type of Risk		✓ Recognised ✓ Hypothetical *and* ✓ Speculative
Substantial Equivalence		✓ No: Technology-based
Science or Other in Risk Assessment		✓ All four regulatory hurdles in risk assessment
Burden of Proof	✓ Traditional: Minimise Type I (Rejected when safe)	
Risk tolerance	✓ Minimum	
Science or Other in Risk Management		✓ Social Dimensions of biotechnology including other legitimate factors in risk management
Specific Regulatory Issues		
Precautionary Principle		✓ Social Interpretation
Focus		✓ Technology-based
Structure		✓ Horizontal, new structures
Participation	✓ Judicial decision-making	✓ Wide, social dimensions
Labelling		✓ Mandatory, technology-based for the consumers' right to know

Table 7.2 EU Regulatory Approach Checklist

With respect to the five regulatory principles for GM crops, the EU approach favours technology-based, horizontal regulations involving wide actor participation and employing the social interpretation of the precautionary principle. In addition, the EU also favours mandatory technology-based labelling policies based on the consumers' right to know the presence of GM material, regardless of the scientific risk assessment of the product.

While the EU regulatory approach has shifted to a social rationality trajectory in response to social interests, it has hindered the competitiveness of the EU agricultural biotechnology and failed to fully address the concerns of social interests. The result is an unstable regulatory approach that is unsatisfactory for both economic and social interests and appears to do very little in ensuring a level of safety and protection above that which prevails in North America under the scientific rationality paradigm.

PART IV ANALYSIS

There are two objectives of Part IV. The first is to bring together Parts I, II, and III in order to analyse why the traditional trade diplomacy approach is incapable of addressing the transatlantic regulatory regionalism associated with GM crops and, hence, stands at a crucial crossroads. The second objective is to take the above analysis a step further and to propose and examine an amended trade diplomacy approach that addresses transatlantic regulatory regionalism in an economically and socially acceptable manner. Essentially, the second objective is to analyse the type of regulatory framework and consequently the type of regulatory integration strategy that trade diplomacy should support in order navigate the fundamental differences in the transatlantic regulatory frameworks and remain a viable force in international integration. While this 'ideal' regulatory framework may then be used to design specific regulations and regulatory procedures, this level of prescription will not be undertaken in this study. Finally, from this 'ideal' regulatory framework follows implications for governments, industry, international governmental organisations and international non-governmental organisations, which will be examined in the last section.

CHAPTER EIGHT TRANSATLANTIC REGULATORY INTEGRATION

8.1 Trade Diplomacy at a Crossroads

This study has focused generally on the trade diplomacy problem of regulatory regionalism and specifically on the problem of transatlantic social regulatory barriers facing GM crops. The thesis is that trade diplomacy stands at a crucial crossroads. Maintaining the traditional trade diplomacy approach that promotes regulatory development and integration from the economic perspective will increasingly erode public support for trade diplomacy and marginalise its ability to facilitate international integration. Amending the traditional trade diplomacy approach to better account for the social dimensions influencing regulations will, instead, enhance the prospects that trade diplomacy can effectively deal with regulatory regionalism and promote international integration. In other words, as trade diplomacy reaches deep into areas of national competence in order to enhance regulatory integration it must be sensitive to the political economy factors shaping the development of the regulatory framework and subsequent regulations within a particular jurisdiction.

This study has revealed that domestic regulations are a function of endogenous political economy factors. These include various interests and events along with the traditional regulatory role of the state and the competitiveness of the jurisdiction with respect to the particular regulatory issue. Specifically, with respect to the development of GM regulations, regulatory instability is the most important policy challenge. This instability is caused by the competing influences of the economic and social perspectives where the former supports scientific rationality and technological progress while the latter supports social rationality and technological precaution. The result is seven debates regarding the regulatory risk analysis framework as well as five specific debates regarding GM crop regulatory principles.

With respect to regulatory integration, this study has revealed that a regulatory jurisdiction faces three integration parameters: the level of integration; the depth of integration; and the strategy of integration (Fig. 8.1). For the regulatory regionalism associated with GM crops the dominant level of integration is the transatlantic level. The integration depth must deliberately target deeper social integration beyond the shallow economic integration favoured in the traditional trade model. The integration strategy must involve proactive regulatory co-ordination and not be limited to reactive regulatory competition only. From Figure 8.1, the proposed regulatory integration

strategy straddles IIC and IID. Therefore, traditional trade diplomacy cannot deal with social regulatory barriers because it is only a very narrow approach to regulatory integration that fails to account for the vital political economy factors that determine social regulations.

		1. Integration Level	
		I. Global/Multilateral	II. Regional/Bilateral or Plurilateral
		3. Integration Strategy	
		Regulatory Competition	Regulatory Co-ordination
2. Integration Depth	Shallow 'Economic' Integration	A	B
	Deeper 'Social' Integration	C	D

Fig. 8.1: Integration Parameters Facing a Regulatory Jurisdiction

In short, this study has so far revealed that traditional trade diplomacy stands at a crucial crossroads. It is clear that in order to remain a viable force in international integration, trade diplomacy must be amended. Essentially, the goal of trade diplomacy must not be to defend the traditional economic integration approach at all costs. Instead, the goal of trade diplomacy must be to encourage international integration in an economically and socially acceptable manner. The objective now is to propose and examine how trade diplomacy may be amended in order to achieve this goal. In the remainder of Chapter 8, the features of an 'Ideal Regulatory Framework' will be discussed (8.2), followed by a discussion of the implications and relevant policy recommendations (8.3).

8.2 Ideal Regulatory Framework

The thesis of this section, following from the analysis of Parts I, II and III, is that a regulatory framework combining the pragmatism of the scientific rationality approach with the responsiveness of the social rationality approach could address the integration challenges of social regulatory barriers to GM crops. This so-called Ideal Regulatory Framework must promote regulatory stability and integration subject to several important parameters. First, the framework must balance the competing economic and social interests calling simultaneously for technological progress and precaution. In this sense, the approach must achieve an acceptable political compromise.

Second, the regulatory framework must be precise enough to be operational. That is, in order to deal with regulatory externalities, eliminate instability and avoid trade tensions, the regulatory framework must have precise rules that clearly outline regulatory procedures. It should avoid vague or ambiguous regulatory principles that lead to delay and indecisiveness.

Third, the regulatory framework must be strategically targeted. The regulatory resources of governments are crucially limited, yet technological innovation is a dynamic phenomenon. In this sense, the regulatory framework must be a dynamic approach focused on the application, management and distribution of GM technology capable of keeping pace with technological innovation, rather than a complete command and control approach that quickly becomes obsolete.

Fourth, with respect to regulatory integration, the regulatory framework must avoid autarky. It must disentangle those regulatory aspects that can be co-ordinated with regulations in other jurisdictions from those regulatory aspects that, because of crucial domestic pressures, must remain under the complete control of the jurisdiction. Further, it must be considerate of relevant international obligations.

Given these important parameters, the Ideal Regulatory Framework employs a Risk Analysis-type framework to the regulation of GM crops. As identified in Part III, both the North American and the European regulatory approaches are within the Risk Analysis Framework, yet they differ substantially on several important framework principles and specific principles for regulating advanced technologies such as GM crops.

Comparing the North American and the European regulatory approaches reveals the sources of regulatory regionalism. Essentially, while the North American regulations remains congruent with the scientific rationality approach, the European regulations have departed from this trajectory and shifted to a distinctly social rationality approach to regulating GM crops, which tends to be more congruent with its regulatory tradition. Table 8.2 compares the two approaches over the framework and specific regulatory principles identified in Chapter 5.

The comparison in Table 8.2 reveals that the transatlantic regulatory regionalism and social regulatory barriers facing GM crops are caused by structural differences in the regulatory approaches employed in North America and Europe. In order to promote stable regulatory integration, the Ideal Regulatory Framework must

overcome the significant structural regulatory differences in the Risk Analysis approach employed in the two dominant jurisdictions.

	North American Approach	European Approach
Tradition	Regulatory Independence	Regulatory Accountability
Belief	Separation of economic objectives from social objectives because intervention: increases costs and decreases productivity, competitiveness and economic prosperity.	Market is embedded in social factors which cannot be separated from economic factors because intervention: increases participation increasing productivity, competitiveness and economic prosperity.
Authority	Independent Regulators; Fourth Level of Government	Democratically accountable regulators
Effectiveness	Economic interpretation of market efficiency	Political economy interpretation of success in meeting social dimensions: Social responsiveness
Paradigm	Scientific Rationality	Social Rationality
Type of Risk	Recognised or hypothetical	Recognised, Hypothetical *and* Speculative
Substantial Equivalence	Yes	No
Science or Other in Risk Assessment	First regulatory hurdle based on identified safety or hazard risk	All four regulatory hurdles
Burden of Proof	Traditional	Traditional; pressures to reverse
Risk tolerance	Minimum	Minimum; pressures for zero tolerance
Science or Other in Risk Management	Safety or Hazard-based	Broader socio-economic concerns
Precautionary Principle	Scientific Interpretation	Social Interpretation
Focus	Product-based, Novel Applications	Process- or Technology-based
Structure	Vertical, Existing structures	Horizontal, new structures
Participation	- Narrow, technical experts - Judicial decision-making	- wide: 'social dimensions' - Judicial decision-making
Labelling	Safety or Hazard only: voluntary, market-based for the consumers' right to know	Mandatory, process-based for the consumers' right to know.
Integration	Regulatory Competition	New Approach: Regulatory Co-ordination and Regulatory Competition

Table 8.1 Comparison of North American and European Regulatory Approaches

Although both Risk Analysis approaches have their strengths, neither approach is the most appropriate for addressing the issue of social regulatory barriers to GM crops. For instance, the North American approach, while supported by economic interests, is simply not socially responsive enough to address social interests and would be vulnerable to a dramatic public crisis over GM foods as has occurred in the UK. Yet, the EU approach, which has shifted to meet the demands of social interests has failed to establish an approach supported be either economic or social interests. It does not have a solid enough foundation of risk assessment to be stable and

predictable and is constantly reacting to perceived risk regardless of the scientific justification for the public concern. Therefore, both approaches must be amended to more equitably address the legitimate economic and social interests in a stable, transparent and socially responsible manner.

The Ideal Regulatory Framework aims to be socially responsive in the regulatory development process but not to the detriment of regulatory framework stability and integration. The key to this is to employ the scientific rationality approach to risk assessment, providing a solid foundation for risk, yet to employ the social rationality approach to risk management, providing a socially responsive framework to meet social interests. Beck (1992) argues that despite the apparent mutual exclusivity of the scientific and social rationality paradigms, they can be integrated because they are mutually reinforcing: "scientific rationality without social rationality remains empty, but social rationality without scientific rationality remains blind".

In short, the Ideal Regulatory Framework essentially builds *social credence* into the scientific rationality paradigm. This is accomplished by combining a scientific risk assessment approach with a social risk management approach and a transparent risk communication strategy. This Ideal Risk Analysis-based Regulatory Framework will be discussed below in its three constituent parts: risk assessment, risk management and risk communication.

8.2.1 Risk Assessment

The objective of risk assessment procedures is to produce neutral and transparent risk information to inform the risk management process. Risk assessment can enhance regulatory stability and regulatory integration by producing clear and precise procedures establishing minimum essential requirements (MERs) for safety applicable in all regulatory jurisdictions.

In order to integrate the scientific and social rationality paradigms in the risk assessment procedures, the only principle of scientific rationality that must be abandoned is the idea that empirical questions are logically prior to normative questions. The reason for this is that a decision must be made as to the type of risk that the risk assessment will focus on. This is a normative question that is in fact prior to the empirical question. But once it is made, empirical questions may be asked and

assessed by recognised experts in the field, resulting in legitimate, credible, neutral and transparent risk information to assist in the risk management procedure.

With respect to the type of risk targeted in risk assessment, the focus of risk assessment must be on asking empirical questions about hypothetical risks, not speculative risks. In other words, risk should be something that can be defined empirically and is testable with empirical means rather than based on unsubstantiated logical possibilities. Empirical questions have the important ability to clarify risk according to accepted analytical methods and causal-consequence mechanisms, while limiting the social and political influence over the risk assessment procedure.

Is this approach acceptable? Indeed, even within the scientific community there is considerable disagreement over empirical conclusions. Yet, disputes among hypothetical risks can at least be assessed through further study and analysis. In fact, it has been argued that this is the approach used in medical risk assessment and it enjoys widespread confidence from all stakeholders (Balk, 1993). Speculative risks based on logical possibilities cannot be 'refuted' by the scientific process and are the refuge of those uninterested in a genuine risk dialogue. In this sense, speculative risks are not an operational regulatory principle.

Focusing on hypothetical risks because they are subject to accepted analytical methods does not mean that new analytical methods cannot be developed nor does it imply that 'no evidence' means 'no risk'. It has been argued that the problem with current Risk Analysis approaches to GM crops is the lack of a predictive ecology framework (Rogers, 1993; CIELAP, 1997). Without such a framework, critics argue that they must bypass risk assessment based on hypothetical risks and rely instead on risk management that assumes speculative risks. Yet, this approach adds nothing to risk information and seems to undermine the development of an alternative analytical method because of the lack of research and development. Indeed, it would be irresponsible to abandon biotechnology because biotechnology and genetically modified organisms are an inevitable feature on the industrial landscape. Developments in biotechnology in general benefit specific applications, hence, technology will continue, even with a ban in one specific area such as agricultural biotechnologies. Also, due to the significant economic stakes of agricultural biotechnology, a regulatory ban in one jurisdiction will only lead to a redistribution of GM crop development, not a halt. It is in the interest of the most advanced nations, with the most advanced scientific capacity and regulatory systems to regulate the

hypothetical risks of GM crops according to the best analytical methods at their disposal in order to set the global standards.

Further, when scientific risk assessments do not yield conclusive results, it is an imperative part of the scientific precautionary approach that no evidence from inconclusive results implies more investigation, and not a conclusion of no risk. Therefore, the development of new analytical methods, such as predictive ecology, must be a regulatory priority. The new methods may prove that past hypothetical risks were under-estimated, however, they may equally prove that past hypothetical risks were over-estimated as they were at the initial Asilomar Conference in 1975.

With respect to the risk assessment debate regarding the principle of substantial equivalence of some GM crops, there appears to be no scientific or moral reason to assert that production improving and some output improving GM crops are not substantially equivalent to non-GM varieties for regulatory purposes. Instead, from a regulatory perspective, risk assessment should be focused on the hypothetical risks of the novel features GM crops, not on the use of genetic modification per se. This is similar to long-standing regulatory control over exotic plants and pests regulated according to their novelty. Hence, from a regulatory perspective it is reasonable to conclude that GM and non-GM crops are substantially equivalent unless the GM crops are novel. This should not be interpreted, however, to mean that consumers do not have a right to know whether a crop is GM or conventional. Of course, if consumers want to know they must have access to this information. In this sense, substantial equivalence is only a useful principle for establishing the necessary level of regulatory oversight for risk assessment, but it cannot be a dominant principle for establishing risk management responses. Instead, the consumers' right to know must be an important principle in risk management, which is discussed in greater detail below (8.2.2).

Should risk assessment focus on other legitimate factors? In risk assessment, where the goal is to develop empirical questions to gain neutral, transparent and credible information about the hypothetical risks of GM crops, there is no role for the normative 'other legitimate factors' including food quality and socio-economic impacts. That is, once the definition of risk is established, a science-basis predicated on hypothetical risks and the best available analytical methods should be the only factors in risk assessment. Risk assessors should only be charged with ensuring a food is safe, not assuaging consumer fears and proving social benefit.

With respect to the debate over the regulatory principle of burden of proof, a logical and legitimate compromise is to maintain the traditional burden of proof (minimise the risk that a technology is rejected when it is in fact safe) but regulate new technology more stringently. However, this is then a risk management activity and will be discussed in greater detail below (8.2.2).

Participation in the risk assessment procedures must be reserved for experts only and the real issue is finding independent and credible scientific experts to perform the hypothetical risk assessment; a process requiring considerable consensus building (Mackenzie, 1993). The experts must be as independent of industry as possible and can include known supporters and critics. This ensures wide participation among the experts and ensures that broad concerns will remain on the agenda. Yet, at the same time, the involvement of scientific experts decreases the variance in normative preferences. Decision-making by the participants must be judicious and rules-based, not consensus-based, in order to ensure timeliness in risk assessments in a field characterised by rapid technological innovation. Finally, the deliberations and decisions of participants must be fully transparent to all interested stakeholders.

The ideal risk assessment procedures are more congruent with the North American approach than the European approach and are generally supported by the OECD, the WHO and the FAO. In this sense, the European approach must shift towards a rules-based and science-based risk assessment procedure for GM crops adopting the scientific interpretation of the precautionary principle and limiting the risk assessment to short- and long-term human and environmental safety, not to other legitimate factors. It must also adopt a product or application-based focus. In addition, it also must increase the transparency of the assessment procedures and it must resist the temptation to overturn assessment decisions that are incompatible with political decisions. Making these amendments solves the European problems of instability and inoperability.

Although largely congruent with the North American approach, the ideal risk assessment procedures do require the North American approach to include greater participation in the procedures. Experts from a broader range of interests, yet familiar with the specified frame of reference and the analytical methods, would participate and wield policy power, not just the GM crop developers and government regulators.

The ideal scientific risk assessment procedures benefit both regulatory stability and integration. Stability is increased because the language of risk, safety and

precaution is harmonised, eliminating confusion and ambiguity associated with divergent risk assessments and effectively levelling the playing field for all stakeholders. Technological precaution is explicitly built into the assessment procedures through risk averse assumptions and likelihood functions allowing credence goods to shift to experience and search goods in a controlled manner. Non-market regulatory objectives, such as human and environmental safety would be dealt with by specifying the frame of reference at the outset establishing regulatory floors based on shared MERs. Participation would be greatly increased making critics part of the scientific risk assessment procedure rather than excluded actors claiming unsubstantiated risks from outside the regulatory development process.

The prospects for regulatory integration are also increased because of the harmonised risk assessment procedures. This limits the problem that could arise because there is no supranational institution to decide on MERs. It also limits the degree of possible normative disagreement because scientific disagreements can be dealt with subject to accepted rules of scientific debate. Essentially, the ideal risk assessment procedures establish regulatory principles that are operational in an international integration framework because the conditions for risk information are precise and stable.

The likelihood that both the North American and the European regulatory approaches can and would adopt the ideal scientific risk assessment procedures are good, despite the necessary modifications. The analysis of the economic and social interests has revealed that in most instances opposition to GM crops is not actually opposition to the technology per se. Instead, it is opposition to the application of the technology. The ideal scientific risk assessment focuses on the risks of these application issues rather than obfuscating the debates by widely condemning the technology of genetic modification. Further, in both regions there is a desire to avoid the 'my scientist v. your scientist' debates which occurred in the WTO beef-hormones dispute. More recently, this debate occurred in the fall of 1999 when British beef approved as safe in Britain and by the EU Food Safety Committee had not been approved as safe by French authorities, and France refused to lift its ban on British beef. Both sides repeatedly claimed that they had science on their side. Adopting the ideal scientific risk assessment procedures would prevent or drastically limit regulatory barriers being justified according to controversial debates over science.

8.2.2 Risk Management

While it is necessary to centralise and harmonise the scientific risk assessment procedures, the objective of risk management must be to build social credence into the scientific regulatory approach. Although the goal of the risk management process is risk reduction and prevention, it is undeniably an inherently political exercise of balancing the rights and interests of both supporters and critics. In this sense, it is incorrect to characterise risk management as just a process of creating economic instruments to correct market failures where the only indicators of regulatory effectiveness are economic measures of market efficiency. In other words, once based on a common framework of risk information, risk management decisions must retain the freedom to be socially responsive.

An important feature of the risk management stage is that endogenous or internal pressures lock risk management at the national level. Essentially, the economic and social stakes are too high to give up authority over risk management. Therefore, it is impractical to expect an international regulatory approach to emerge in the short or even medium term. Instead, risk management remains the domain of regulatory jurisdictions and cannot be effectively centralised or harmonised at the multilateral level.

Within this context, the ideal risk management process aims to ensure that regulatory development, while being socially responsive, is simultaneously considerate of both the scientific risk assessment procedures and the obligations to other countries under various international agreements.

Under the ideal risk management process science matters and the risk management deliberations must be based on a common foundation of informed risk information provided by the risk assessment procedure. With respect to the regulatory debate associated with risk tolerance, risk management must accept that zero tolerance is not a realistic goal. Instead, the focus must be on the relative risk of the GM crop application subject to some tolerated level of risk permitting the technological progress necessary to increase risk information. Without this basis, risk management is arbitrary and vulnerable to both regulatory capture and to criticisms that it is scientifically unjustifiable. One solution is to introduce a "technology penalty" (van den Daele *et al.*, 1997) at the risk management stage designed to build consumer confidence in the regulatory control over new technologies. In fact, it has been argued that greater scrutiny of GM crops has already been established in this way, without

having to reverse the burden of proof. Ager (1990) and Fincham and Ravetz (1991) both argue that GMOs have faced greater regulatory scrutiny in the UK despite the fact that there is no empirical evidence to justify this. In this case, risk management regulations are primarily for confidence building to address the credence factors and not for enhancing safety. Yet, given the discussion on the UK (Chapter 7.3.1) it is clear that the technology penalty must also be accompanied by a more concerted effort by proponents to address the information gap created by the commercialisation of their own applications. In essence, the burden of proof remains the traditional principle, but the new technology must meet more stringent conditions on product or application performance and on dealing with credence factors.

Therefore, unlike risk assessment, science cannot be the final arbiter of risk management, it can only inform the regulatory development process. With respect to the risk management debate over the use of science or other legitimate factors, the ideal risk management must consider the social dimensions of GM crops and involve the participation of all stakeholders from either end of the support – opposition spectrum. In this sense, risk management cannot be independent or normative-free because it cannot be disentangled from the interests and concerns of both supporters and critics.

Crucially, this requires compromise and concession on the part of both supporters and critics and the realisation that the goal of risk management is not to build normative consensus, rather it is only to strike an acceptable balance. On one hand, private firms must endeavour to assess GM crops to the highest level of consumer and environmental protection available. They also must respect the social dimensions and credence nature of GM crops by meeting the consumers' right to know, even in the absence of safety issues. Recall from Chapter Two that the failure to preserve consumer choice among GM and non-GM crops has had disastrous consequences in Europe, despite the absence of safety issues or justifications. In addition, product liability laws should be included in regulatory approaches to make sure that the risk to human and environmental safety becomes internalised by the firm as commercial risk, which the firm then minimises. Indeed, it has been argued that with product liability laws "regulators may have significantly more freedom... in coercing the market toward efficient outcomes" (Holloway, 1999).

On the other hand, critics cannot expect regulatory approaches to fully reflect their belief systems and must be prepared to compromise without illegal action. They

must participate in and respect the risk information provided in the risk assessment procedure and some level of risk tolerance must be accepted in risk management, as there is no such thing as zero risk. They must be prepared to engage in co-operative, non-antagonistic actions during the risk management process.

The ideal risk management process also requires governments to abandon the inward focus common for food safety and environmental protection regulation. Instead, governments must give equal consideration to the impact of their risk management decisions upon other countries as well according to their obligations under various international agreements. There is no such thing as 'autarky', and as regulations impact market access, risk management policies must consider those impacts. Governments must resist domestic pressures to impose regulatory barriers unjustified according to either the scientific risk assessment or to acceptable measures agreed to in, for example, trade agreements.

To achieve this, mutual recognition must be built into the domestic risk management process. The reason for this is because domestic regulations represent a political balance and once a balance is achieved, it is crucial for the political stability that regulatory framework prevents foreign GM crops from circumventing the domestic requirements, thus creating concerns which destabilise the balance. If governments cannot resist establishing unjustified regulatory barriers than they must be prepared to acknowledge that the barriers are driven by unjustified factors in violation of the international obligations. Hence, although governments can opt out of their obligations, they cannot do so without cost, in this case, paying compensation to affected foreign firms in a manner which they have already agreed under international agreements. In this sense, national governments are free to choose whatever risk management regulatory response they wish, but they are not free to use controversial scientific justifications.

Additionally, the intergovernmental discussions on mutual recognition must abandon traditional trade diplomacy features such as limited participation and untransparent, closed door discussions. Instead, discussions of mutual recognition must occur with both an open dialogue and wider participation. The key result of the open, transparent mutual recognition strategy is that while national governments are free to pursue those regulatory responses that are domestically necessary, they must accept the regulatory responses of other governments as equivalent to their own. Of course, this further supports the centralisation of scientific risk assessment procedures

so that a domestic government can ensure that the safety assessments are domestically acceptable.

The ideal risk management process is more congruent with the European regulatory accountability approach where regulatory development responds to the social dimensions, not just to market failures. In order to achieve the ideal risk management process, the European approach must fully commit to scientific risk assessment procedures as an important foundation for risk management and it must be prepared to support a level of tolerable risk, even in the face of public pressure. Further, social risk management decisions taken in absence of a scientific justification must be considered in the context of international rights and obligations where contravention, although permissible, is not without cost.

Meanwhile, the North American regulatory approach must accept the legitimacy of other factors in risk management, beyond scientific factors. In other words, it must accept a social risk management process. This includes provisions to address the credence nature of GM crops by permitting regulations predicated on the consumers' right to know, even in the absence of safety concerns. For instance, this means that non-product-related PPM based labelling rules must be developed and accepted and not challenged under narrow international trade law that fails to adequately account for a social approach to risk management.

Essentially, in dealing with regulatory barriers to trade the ideal risk management process is crucially focused on building social credence into the scientific rationality approach. It accepts the fact that regulations are political and that political factors differ between countries and regions making it impossible to establish international risk management responses. Divergence in regulatory approach will occur, but this divergence will be minimised by basing risk management on centralised scientific risk assessment procedures. Further, the proactive regulatory co-ordination strategy of mutual recognition prevents the tensions and disputes that arise under regulatory competition.

The ideal risk management approach can increase regulatory stability by ensuring that it is based on a foundation of credible, harmonised scientific risk assessments procedures. It preserves sovereignty or autonomy over regulatory responses meeting crucial subsidiarity pressures. It acknowledges the critical role of political and social factors in regulatory development and it supports the legitimacy of these other factors beyond the limited market failure and scientific factors.

The ideal risk management approach also enhances regulatory integration through regulatory co-ordination by promoting co-operative, proactive efforts to develop mutual recognition agreements avoiding the forced convergence of regulatory competition. Mutual recognition avoids both the difficulties of harmonising risk management across countries and regions with divergent economic, social and political factors and the potential democratic deficit created when international institutions wield regulatory authority in the absence of clear accountability provisions. It promotes greater commercial certainty through stable market access rules creating economies of scale and reducing transactions costs. Although this strategy cannot prevent regulatory barriers it can discipline their use in a framework more capable of meeting the concerns that make disciplining regulatory barriers under a regulatory competition framework at the WTO unacceptable. Finally, the ideal risk management process can prevent a competitive deregulation or regulatory race to the bottom because it explicitly provides for the inclusion of legitimate, non-market objectives in domestic regulatory responses.

8.2.3 Risk Communication

The biggest failure with the Risk Analysis framework in both North America and Europe has been a lack of transparency; the failure to provide adequate and accurate risk communication. GM crops exhibit credence factors poorly understood by consumers because of a significant information gap. Both supporters and critics have failed to provide accurate information, and instead have manipulated information to meet their own interests. Consider, for instance, supporters and their global welfare promises and critics and their sensational dread predictions based on emotive, speculative risks. Governments, pulled in opposite directions to meet the interests of both supporters and critics, have understandably chosen to quietly deal with GM crops in an attempt to keep them out of the political agenda. Together, the polarity of views and the untransparent government approach represent a completely unacceptable strategy of risk communication.

The ideal risk communication strategy is a complete commitment, by all stakeholders to the two-way flow of transparent information between scientific risk assessment procedures and the risk management process. The risk information produced in the scientific risk assessment procedures must be available to all interested stakeholders, including interested parties in other countries. To make this

possible, GM crop developers must abandon both their global welfare promises and their over-used claims of 'proprietary information'. Consumers have a right to know and a lack of transparency is easily construed to imply that there is something to hide. Providing the results of in-house human and environmental risk assessments does not reveal crucial proprietary knowledge, but it does significantly limit the vulnerability of firms to spurious, sensational criticisms. Further, the results of the scientific risk assessment procedures, as well as the deliberations must be completely available to all stakeholders in the risk management process. In turn, however, the social dimensions of the risk management process must also flow back into the scientific risk assessment procedures in terms of the scientific precautionary principles, for instance.

The goals of the ideal risk communication strategy are to reduce the information-gap caused by the credence nature of GM crops and to increase public confidence in the regulatory approach. To achieve this the North American approach must accept that the risk communication of GM crops must meet the consumers' right to know about the non-safety aspects. The European approach must increase its transparency to eliminate the unacceptable regulatory hold-up without explanation. Both approaches must better acknowledge the unavoidable regulatory externalities or global aspects of GM crops. By addressing the credence nature of GM crops, the polarity is minimised resulting in informed consumerism based more appropriately on the actual benefits and risks, and fully in support of consumer choice. Given the enormous economic, human health and environmental benefits it is difficult to believe that consumers, truly informed, would reject GM crops. Instead, they would understand that it is the application that matters and that applications are best controlled through a risk management framework. In short, the ideal risk communication strategy enhances stability and integration by enhancing transparency and public confidence.

8.3 Conclusion and Implications

The Ideal Regulatory Framework essentially builds social credence into the scientific rationality approach resulting in a stable framework congruent with deeper social integration according to a regulatory co-ordination strategy. Social credence is built in by ensuring consumer information, trust and choice. This approach meets the prerequisites of balancing the competing interests within an operational, dynamic, rules-based approach capable of managing the applications of advanced technologies.

There are significant implications of this Ideal Regulatory Framework upon governments, the GM crop industry, international organisations and non-governmental actors, which will be discussed below in this order.

8.3.1 Implications for Governments

Within the transatlantic regulatory regions, governments must reconcile the divergence in their regulatory frameworks. With respect to risk assessment procedures, the EU approach must become more like the North American approach while for the risk management process the North American approach must become more like the EU approach with greater stakeholder participation. For risk communication, both the North American and EU approaches must endeavour to be more transparent and accessible.

In dealing with the problem of regulatory integration, governments must engage in proactive regulatory co-ordination, not regulatory competition. In this sense, the North American approach must become more like the EU and could learn a great deal from the European experience with integrating economies. Also, recognising the severe weaknesses in dealing with regulatory integration, governments must refuse to take disputes over social regulatory barriers to the WTO.

The Ideal Regulatory Framework allows countries to unilaterally pursue their own social regulatory approaches and they may even ban GM crops if they wish according to the scientific interpretation of the precautionary principle. However, it prevents them from misusing 'science' in order to support domestic political concerns and holds them accountable to obligations that they have already agreed to under international treaties.

8.3.2 Implications for the GM Crop Industry

The GM crop development industry in both North America and Europe must accept both that regulations are not instruments used only to correct market failures and that consumers are not just economic agents. Instead, regulations play a legitimate, crucial role in meeting broader social concerns and they must not be viewed only as economic costs. The industry must take a proactive role in addressing the information-gap associated with their products through accurate and transparent risk communication. The consumer does have a right to know whether or not products are derived from GM crops. In meeting this right, industry must endeavour to identity

preserve, regardless of the incremental costs. As segregation is necessary for both output trait GM varieties and Bio-engineered products, this simply speeds up the introduction of effective segregation procedures.

Industry must also accept that science cannot be the final arbiter and, instead, there must be scope for the use of the scientific interpretation of the precautionary principle in regulatory approaches. The scientific precautionary principle is a legitimate regulatory objective and it may be used to restrict or ban particular GM crop varieties.

Finally, industry must accept that the comprehensive range of concerns associated with GM crops requires an international regulatory integration approach broader in remit than the traditional trade approach. In this sense, industry must accept that the WTO cannot be the dominant international institution and they must be prepared to avoid using the WTO to adjudicate on the appropriateness of domestic risk management regulations. Therefore, industry must engage fully in a regulatory co-ordination strategy through, for instance, simultaneous approval applications in North America and the EU in order to highlight the common, shared objectives rather than the differences. Moreover, they must accept the social need for international protocols focused more on socio-economic issues, such as the Biosafety Protocol.

8.3.3 Implications for International Institutions

International organisations must facilitate regulatory co-ordination where possible, and where not possible, must be prepared to stay out of the way. The key lesson is that when the fundamental regulatory framework is unstable and divergent in North America and the European Union there is very little hope that an international regulatory framework will be imposed top-down. The implication of this is that international organisations such as the OECD, Codex along with the WHO and FAO should continue to assist the risk assessment procedures for the safety of GM crops, yet they should avoid involving themselves in the risk management process for fear of tarnishing their independence and credibility.

Similarly, the WTO should be kept out of social regulatory integration when at issue is the development of the fundamental regulatory principles. It cannot credibly rule on which regulatory framework ought to be used because it is fundamentally built on the economic perspective, yet social regulations are most often driven from the social perspective. This is not to say that the WTO is not a valuable institution.

Indeed, it should continue to focus on trade liberalisation through the administration and enforcement of rules and in areas of little controversy it can play a role in brokering international rules. But it should not be charged with establishing the fundamental regulatory framework and adjudicating whether or not social regulations are compatible with trade objectives. Such a role only serves to seriously undermine support and confidence in an otherwise very valuable institution.

Of course, this raises an important question about what to do with the SPS Agreement – a trade agreement right in the middle of the controversy between trade objectives and social regulations. Clearly, the SPS Agreement should not be renounced, but careful guidelines on its applicability must be established. Essentially, it is vital to determine whether or not the regulatory barrier under investigation has created trade tensions because of disagreements over framework principles or specific principles. If, for instance, there is widespread international agreement on framework principles then the trade dispute over specific regulatory interpretations can be reasonably brought to the WTO's dispute settlement mechanism. If, on the other hand, the dispute arises because two jurisdictions disagree on a fundamental framework principle, then it is obvious that the WTO cannot credibly deal with this dispute.

8.3.4 Implications for International Non-Governmental Organisations

The international non-governmental organisations (INGOs) that compose the social interests must accept that regulatory development is a political exercise requiring compromise and concession. While the ideal Risk Analysis Framework amends the regulatory approaches to more effectively deal with their concerns, at the same time, INGOs must be prepared to participate in the entire regulatory development process even if their belief systems are not met in their entirety. For instance, criticisms of the risk assessment procedures can only be considered valid if the organisations are involved in the procedures, rather than raising sensational speculative risks from the sidelines. They must be fully engaged in the risk management process and accept that their interests are not the only ones that regulations must consider. Finally, and perhaps most crucially, they must also commit to an accurate and transparent risk communication strategy with the objective of increasing informed consumerism. They wield enormous power in capturing the media on emotive issues and this power must be wielded responsibly. In fact, their greatest contribution would be as an active participant in the development process,

engaged in finding common ground among the stakeholders, rather than as just a critic on the sidelines.

8.3.5 Looking Ahead

There should be no doubts about the difficulty of meeting the challenge of social regulatory barriers to the trade of GM crops. Dealing with these barriers requires drastic structural changes to the traditional trade diplomacy framework as well as crucial compromise and concession from all involved stakeholders; both supporters and critics. This is not an issue of extremes. Instead, all stakeholders must endeavour to find the elusive common ground of a more reasoned and rational approach. Only then can the benefits of trade liberalisation and socially acceptable regulatory oversight be simultaneously achieved.

Once the transatlantic rules for establishing a regulatory approach capable of balancing technological progress with precaution are developed, the approach must be taken to the international level to begin the process of multilateralisation. Admittedly, this next step is also fraught with enormous challenge because it must reconcile the often-competing interests of developed and developing countries; the so-called North-South divide. In this sense, transatlantic regulatory co-ordination is time-sensitive as perhaps more pressing or urgent North-South issues will continue to be insufficiently addressed until the pillars of the international economic order reconcile their transatlantic differences.

Finally, only when a multilateral regulatory framework is established can the WTO then play its role as the principle trade liberator, clear of the controversies associated with social regulatory integration.

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